Access DB# 57552

SEARCH REQUEST FORM

Scientific and Technical Information Center

Requester's Full Name: William H Matthews Examiner #: 75379 Date: 11/15/00
Art Unit: 3737 Phone Number 305-0316 Serial Number: 09/713,595
Mail Box and Bldg/Room Location: 2B08 Results Format Preferred (circle): PAPER DISK E-MAIL

If more than one search is submitted, please prioritize searches in order of need.

****

Please provide a detailed statement of the search topic, and describe as specifically as possible the subject matter to be searched. Include the elected species or structures, keywords, synonyms, acronyms, and registry numbers, and combine with the concept or utility of the invention. Define any terms that may have a special meaning. Give examples or relevant citations, authors, etc, if known. Please attach a copy of the cover sheet, pertinent claims, and abstract.

Title of Invention: Minimally Invasive Method for Implanting a Sacral Stimulation Lea

Inventors (please provide full names): George Mamo

Michele Spinelli

Earliest Priority Filing Date: 11/15/00

***For Sequence Searches Only* Please include all pertinent information (parent, child, divisional, or issued patent numbers) along with the appropriate serial number.**

See claims ~~1, 2, 5, 6, 8, 9~~ new

17, 19, 20, 22, 23, and 26.

****

STAFF USE ONLY	Type of Search	Vendors and cost where applicable
Searcher: JEANNE HARRIGAN	NA Sequence (#)	STN
Searcher Phone #: 305-5934	AA Sequence (#)	Dialog ✓
Searcher Location: CP2-2C08	Structure (#)	Questel/Orbit
Date Searcher Picked Up: 1-7	Bibliographic ✓	Dr.Link
Date Completed: 1-8	Litigation	Lexis/Nexis
Searcher Prep & Review Time: 178	Fulltext	Sequence Systems
Clerical Prep Time:	Patent Family	WWW/Internet ✓ (Limited search to Medtronic)
Online Time: 32	Other	Other (specify)

PTO-1590 (1-2000)

January 8, 2002

TO: William Matthews, Art Unit 3738

FROM: Jeanne Horrigan, EIC-3700

SUBJECT: Search Results for Serial #09/713598

Attached are the search results for "Minimally Invasive Method for Implanting a Sacral Stimulation Lead," including results of an inventor search in foreign patent databases, and prior art searches in foreign patent and sci/tech/medical non-patent databases.

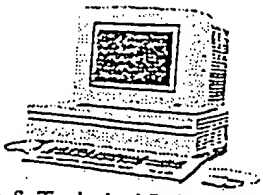
I tagged the items that seemed to me to be most relevant, ***but I suggest that you review all of the results***.

I hope these results are useful. Please let me know if you would like me to expand or modify the search or if you have any questions.

Also attached is a "*Search Results Feedback Form*." Your feedback will help enhance our search services.

EIC3700/2900

Search Results Feedback Form (Optional)



Scientific & Technical Information Center

The search results generated for your recent request are attached. If you have any questions or comments (compliments or complaints) about the scope or the results of the search, please *contact the EIC searcher who performed your search (or either of us):*

John Sims, Team Leader, 308-4836, CP2-2C08
or Jeanne Horrigan, Searcher, 305-5934

Voluntary Results Feedback Form

- *I am an examiner in Workgroup:* ☐ *Example:* 3740
- *Relevant prior art found, search results used as follows:*
  - ☐ 102 rejection
  - ☐ 103 rejection
  - ☐ Cited as being of interest.
  - ☐ Helped examiner better understand the invention.
  - ☐ Helped examiner better understand the state of the art in their technology.

Types of relevant prior art found:

- ☐ Foreign Patent(s)
- ☐ Non-Patent Literature
  (journal articles, conference proceedings, new product announcements etc.)

- *Relevant prior art not found:*
  - ☐ Results verified the lack of relevant prior art (helped determine patentability).
  - ☐ Search results were not useful in determining patentability or understanding the invention.

Other Comments:

Drop off completed forms in the inbox, EIC 3700/2900, CP2-2C08, or in CPK1-5A02. Thanks!

File 350:Derwent WPIX 1963-2001/UD,UM &UP=200201
File 344:CHINESE PATENTS ABS APR 1985-2001/Oct
File 347:JAPIO OCT 1976-2001/Aug(UPDATED 011203)
File 371:French Patents 1961-2001/BOPI 200151

Set	Items	Description
S1	1133	NEUROSTIMULAT??? OR NEURO()STIMULAT??? OR STIMULAT???(3N)N-ERVE? ?
S2	23888	URIN?
S3	761	FECAL?
S4	3157	SEXUAL
S5	91	PELVIC()(PAIN OR FLOOR)
S6	37	S1 AND S2:S5
S7	37	IDPAT (sorted in duplicate/non-duplicate order)
S8	37	IDPAT (primary/non-duplicate records only)
S9	37	S6
S10	37	IDPAT (sorted in duplicate/non-duplicate order)
S11	**37**	**IDPAT (primary/non-duplicate records only)**

11/TI,PY,PN/2 (Item 2 from file: 350)
DIALOG(R)File 350:(c) 2002 Derwent Info Ltd. All rts. reserv.
Recording probe for quantifying nerve and neural-muscular integrity related to pelvic organs or pelvic floor functions, has distensible sheath, distal recording electrode, and inflatable balloon
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 200152729	A2	20010726	WO 2000US34719	A	20001220	200149 B

Patent No	Kind	Date	Week
WO 200152729	A2	20010726	200149 B

Abstract (Basic): WO 200152729 A2

11/7/5 (Item 5 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2002 Derwent Info Ltd. All rts. reserv.
013869978
WPI Acc No: 2001-354190/200137
Neuromodulation therapy of sacral nerves, for urinary incontinence and urological disorders, comprises implantable lead-receiver and external stimulator having power source, controlling circuitry and predetermined programs
Patent Assignee: BOVEJA B R (BOVE-I)
Inventor: BOVEJA B R
Number of Countries: 001 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 20010002441	A1	20010531	US 98178060	A	19981026	200137 B
			US 2000752083	A	20001229	

Priority Applications (No Type Date): US 2000752083 A 20001229; US 98178060 A 19981026
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 20010002441	A1		22	A61N-001/36	CIP of application US 98178060 CIP of patent US 6205359

Abstract (Basic): US 20010002441 A1
NOVELTY - Neuromodulation therapy for urinary incontinence and urological disorders, **comprises an implantable lead-receiver and an external stimulator having power source, controlling circuitry and predetermined programs.**

DETAILED DESCRIPTION - An apparatus for neuromodulation of the sacral nerves, comprises:

(a) an implantable lead-receiver comprising a secondary coil and electrode(s) capable of stimulating a sacral nerve ;

(b) an external stimulator comprising a power source, circuitry to emit electrical signals, at least two predetermined programs to control the electrical signals, and a primary coil;

(c) the primary coil and the external stimulator and the secondary coil of the implantable lead-receiver are capable of forming an electrical connection by inductive coupling.

The external stimulator is capable of controlling the stimulation of the sacral nerve .

INDEPENDENT CLAIMS are also included for:

(1) a method to provide therapy for at least one of: urinary incontinence, neurological disorders, bladder control, bladder inflammation and bladder pain such as may be caused by interstitial cystitis disease. The method comprises: (a) providing the implantable lead-receiver and external stimulator as above; (b) activating the programs of the stimulator to emit the electrical signals to the external coil; and (c) inductively transferring the signals to the secondary coil of the lead-receiver. The electrical signals stimulate the sacral nerve according to predetermined programs; and

(2) a method for neuromodulating the sacral nerves. The method comprises: (a) selecting a predetermined program to control the output of the external stimulator; (b) activating the external stimulator to emit electrical signals according predetermined program; and (c) inductively coupling the external stimulator with an implantable lead-receiver to stimulate a sacral nerve .

USE - The apparatus and methods are useful for neuromodulation therapy for urinary incontinence, neurological disorders, bladder control, bladder inflammation and bladder pain such as may be caused by interstitial cystitis disease.

ADVANTAGE - The stimulation of the sacral nerve via electrical stimulation inhibits inappropriate neural reflex behavior. The patient is able to select and alter program for their comfort without going to the physician's office. The system is cheaper and can be manufactured for a fraction of the price of an implantable pulse generator. The implanted circuit does not have battery and this eliminates need for surgical replacement.

pp; 22 DwgNo 0/14
Derwent Class: A96; B07; D22; P34; S05
International Patent Class (Main): A61N-001/36

11/7/10 (Item 10 from file: 350)
DIALOG(R)File 350:Derwent WPIX

013192304 **Image available**
WPI Acc No: 2000-364177/200031
Implantable medical lead for non-direct contact electrical stimulation of sacral nerve, has a pair of electrode contacts which provide stimulation to sacral nerve without being in contact with sacral nerves
Patent Assignee: MEDTRONIC INC (MEDT)
Inventor: GERBER M T
Number of Countries: 026 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week

US 6055456 A 20000425 US 99301937 A 19990429 200031 B
EP 1048321 A2 20001102 EP 2000108055 A 20000420 200056
Priority Applications (No Type Date): US 99301937 A 19990429
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
US 6055456 A 7 A61N-001/05
EP 1048321 A2 E A61N-001/05
Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI
Abstract (Basic): US 6055456 A

NOVELTY - A pair of electrode contacts (20,40) are provided at the distal end (25) of lead body (15). The electrode contact (20) comprising a coiled wire extends longitudinally towards the proximal end (35) of lead body, such that it does not overlap with the contact (40). **The two contacts provide stimulation to the sacral nerve without being in direct contact with the sacral nerves.**

DETAILED DESCRIPTION - The electrode contact (40) comprises a solid surface material such as platinum or platinum-iridium or stainless steel. The electrode contact (20) begins at the distal end, having either conductive or non-conductive tip, with a length of 0.4 inch. The electrode contact (40) has a length of 0.03-1.0 inches.

USE - For non-direct contact electrical stimulation of sacral nerves to rectify urinary incontinence, urinary urge, urinary retention, pelvic pain , bowel dysfunction and erectile dysfunction also used in muscle stimulation such as dynamic **graciloplasty**.

ADVANTAGE - Time for implantation of the lead 5-10 minutes and the usage of smaller diameter lead allows less invasive implantation. The lead simplifies implant procedure and eliminates the need to reprogram the stimulation levels or reopen the patient to move the head. Implanting the lead near sacral nerves with less specificity, reduces implantation time. The electrode contacts allow the lead to be placed in a less precise manner, while providing adequate electrical stimulation to the sacral nerve . Since the electrode is not in direct contact with the nerve, a small amount of movement from original implant position does not reduce the nerve capture. Allows physician to use a local anesthesia instead of general anesthesia, thus reducing the danger inherent with the use of general anesthesia.

DESCRIPTION OF DRAWING(S) - The figure shows the implantable lead with two electrode contacts.

Lead body (15)
Electrode contacts (20,40)
Distal end (25)
Proximal end (35)
pp; 7 DwgNo 3/6

Derwent Class: P34; S05
International Patent Class (Main): A61N-001/05

11/7/12 (Item 12 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2002 Derwent Info Ltd. All rts. reserv.
012988855 **Image available**
WPI Acc No: 2000-160708/200014
Urinary incontinence treatment method utilizing implantable micro stimulators
Patent Assignee: ADVANCED BIONICS CORP (ADBI-N)
Inventor: LOEB G E; MANN C M; RICHMOND F J R
Number of Countries: 023 Number of Patents: 003

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200001320	A2	20000113	WO 99US14775	A	19990629	200014	B
AU 9949635	A	20000124	AU 9949635	A	19990629	200027	
EP 1100402	A2	20010523	EP 99933612	A	19990629	200130	
			WO 99US14775	A	19990629		

Priority Applications (No Type Date): US 9891762 P 19980706
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200001320	A2	E	16	A61F-000/00	

Designated States (National): AU CA JP US
Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

AU 9949635	A		A61F-000/00	Based on patent WO 200001320
EP 1100402	A2	E	A61F-002/00	Based on patent WO 200001320

Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

Abstract (Basic): WO 200001320 A2

NOVELTY - The micro stimulators are programmed using radio-frequency control via an external controller that can be used by physician to produce patterns of output stimulation pulses judged to be efficient at reducing effect of incontinence, by stimulating nerve pathways (8) that diminish involuntary bladder contractions.

DETAILED DESCRIPTION - Method includes injection or laparoscopic implantation of battery-powered or radio frequency-powered micro stimulators (10) lodged beneath the skin of the perineum. The stimulation program is retained in the micro stimulator device or external controller (20) and transmitted when commanded to start and stop by signal from patient.

USE - For treatment of urinary incontinence.

ADVANTAGE - Allows patient to be taught to receive one or more patterns of neural stimulation. Improves closure of bladder outlet, and long-term health of urinary system by increasing bladder capacity.

DESCRIPTION OF DRAWING(S) - Drawing shows programming system for use with implantable micro stimulator.

Stimulating nerve pathway (8)
Battery powered micro stimulator (10)
External controller. (20)
pp; 16 DwgNo 1/2

Derwent Class: P32; S05
International Patent Class (Main): A61F-000/00; A61F-002/00

11/7/16 (Item 16 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012672477 **Image available**
WPI Acc No: 1999-478584/199940
Programmable cavernous nerve stimulator for treatment of impotency
Patent Assignee: CYBERNETIC MEDICAL SYSTEMS CORP (CYBE-N)
Inventor: ARDITO J R; KNOLL L D
Number of Countries: 001 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
US 5938584	A	19990817	US 97970673	A	19971114	199940	B

Priority Applications (No Type Date): US 97970673 A 19971114
Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes
US 5938584 A 8 A61F-005/00
Abstract (Basic): US 5938584 A

NOVELTY - A polarized magnetic reed switch is activated by an external magnet to supply or disconnect power to the oscillator and the output amplifier from a battery. An implantable elongated bipolar lead (10) has electrodes (12,14) for delivering generated pulse. A microprocessor is coupled to a generator to adjust width, frequency and amplitude of the generated pulse.

DETAILED DESCRIPTION - An implantable pulse generator, consisting of an oscillator and a preamplifier, produces pulses of a desired width, frequency and amplitude. A telemetry link is provided in the microprocessor to receive a programming signals from an external programming device.

USE - For treatment of impotency.

ADVANTAGE - Facilitates erection without any side effects. Enhances battery life by using magnetic reed switch to control drainage of power from battery. Facilitates spontaneous sexual relations. Eliminates need for any external device.

DESCRIPTION OF DRAWING(S) - The figure shows a perspective view of cavernous nerve stimulator .

Bipolar lead (10)
Electrodes (12,14)
pp; 8 DwgNo 1/4

Derwent Class: P32; S05; U22
International Patent Class (Main): A61F-005/00

11/7/25 (Item 25 from file: 350)
DIALOG(R)File 350:Derwent WPIX

010590016 **Image available**
WPI Acc No: 1996-086969/199609
Anchor for securing nerve stimulation lead to sacrum - has lead fixing sleeve connected to base with bone fastener holes and distributor for stress from fasteners, and avoids need to remove any bony protrusions
Patent Assignee: MEDTRONIC INC (MEDT)
Inventor: KNUTH H M
Number of Countries: 001 Number of Patents: 001
Patent Family:
Patent No Kind Date Applicat No Kind Date Week
US 5484445 A 19960116 US 93135108 A 19931012 199609 B
Priority Applications (No Type Date): US 93135108 A 19931012
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
US 5484445 A 7 A61N-001/00
Abstract (Basic): US 5484445 A

An anchor for securing a lead to the sacrum has a base (22) with a mounting hole for a fastener to secure the base to the sacrum, and a lead hole aligned with the lumen of a sleeve (21) mounted to the base and to which the lead (12) can be fixed, with the sleeve and its lumen parallel to the base. There is a member (14) to distribute stress exerted by the fastener (15) on the base and pref. formed as an elongate washer of dog bone shape. The base and sleeve are pref. of pliant material, e.g. silicone or polyurethane and the base includes nylon mesh reinforcement.

Also claimed is an anchor for securing a lead to bone, with a

stress distributor and opt. with a sleeve.
USE - For use in selective nerve stimulation to control urinary and faecal incontinence and penile erection.
ADVANTAGE - The device is simple and reliable, allows the electrode to be properly located while the anchor is installed and does not require removal of any bony protrusions.
Dwg.2/13
Derwent Class: A96; D22; P34
International Patent Class (Main): A61N-001/00

11/7/29 (Item 29 from file: 350)
DIALOG(R)File 350:Derwent WPIX
(c) 2002 Derwent Info Ltd. All rts. reserv.
007498565 **Image available**
WPI Acc No: 1988-132498/198819
Stimulation method for pelvic floor muscles - positioning electrodes on nerve bundles and using them to sequentially apply pulse trains to control organ functions
Patent Assignee: UNIV CALIFORNIA (REGC)
Inventor: GLEASON C A; LUE T; SCHMIDT R; TANAGHO E A
Number of Countries: 002 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
US 4739764	A	19880426	US 86855085	A	19860422	198819	B
CA 1297164	C	19920310				199216	

Priority Applications (No Type Date): US 86855085 A 19860422; US 84611836 A 19840518
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 4739764	A		22		

Abstract (Basic): US 4739764 A
The method comprises the identification of the anatomical location and functional characteristics of selected nerve bundles controlling the separate function of at least one organ, including a person's bladder, rectum and/or associated sphincters. Electrodes are positioned on such nerve bundles for stimulating them while simultaneously isolating adjacent nerve bundles. **Pulse trains are sequentially applied to the electrode to separately control the function of the one organ or a number of organs simultaneously.**
The positioning step comprises attaching two or more electrodes in twenty-one different combinations on selected nerve bundles for modulation purposes and in seven locations on selected nerve bundles for increasing sphincter tonus. ADVANTAGE - Can be carried out bilaterally or unilaterally depending on patients needs.
12/18
Derwent Class: P34; S05
International Patent Class (Additional): A61N-001/36

11/7/37 (Item 37 from file: 371)
000226339
Titre: Procede et appareil pour la neurostimulation electrique de la vessie urinaire neurogene
Deposant: INSTITUT MEDICINA FARMAC
Nom Inventeurs: T. Burghele; V. Ichim; M. Demetrescu
Nom Mandataire: CABINET MALEMONT
Nature de Publication: Brevet

Information de Brevet et Priorites (Pays, Numero, Date):
Numero Publication: FR 2038813 - 19710108
Numero Depot: FR 699561 - 19690331
Priorites: FR 699561 - 19690331
Classification Internationale (Principale): A61N-001/00
Forme Juridique (Type, Date de l'action, No. de BOPI, Description):
Publication 19710108 Date de publication
Delivrance 19710108 7101 Date de delivrance
Decheance 19831130 Date de decheance

File 348:EUROPEAN PATENTS 1978-2001/DEC W02
File 349:PCT FULLTEXT 1983-2002/UB=20020103,UT=20011227

Set	Items	Description
S1	1989	NEUROSTIMULAT??? OR NEURO()STIMULAT??? OR STIMULAT???(3N)N-ERVE? ?
S2	29012	URIN?
S3	3256	FECAL?
S4	4917	SEXUAL
S5	357	PELVIC()(PAIN OR FLOOR)
S6	92	S1(S)S2:S5
S7	60151	IMPLANT?
S8	**12**	**S6 (S)S7**

8/6,PY/3 (Item 1 from file: 349)
DIALOG(R)File 349:(c) 2002 WIPO/Univentio. All rts. reserv.
00789738
TREATMENT OF TISSUE BY APPLICATION OF ENERGY AND DRUGS

8/3,AB/1 (Item 1 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS
(c) 2001 European Patent Office. All rts. reserv.
01110480
System for providing medical electrical stimulation to a portion of the nervous system
System zur Abgabe einer elektrischen Reizung an einem Teil des Nervensystems
Systeme fournissant une stimulation electrique a une partie du systeme nerveux
PATENT ASSIGNEE:
MEDTRONIC, INC., (209272), 7000 Central Avenue N.E., Minneapolis, Minnesota 55432-3576, (US), (Applicant designated States: all)
INVENTOR:
Duysens, Victor P.J., Nieuwstraat 43, 6127 BA Grevenbicht, (NL)
Pearson, Robert M., 2134 Wallingford Lane, Woodbury, Minnesota 55125, (US)
Bonde, Eric H., 1617 Woodstone Drive, Victoria, Minnesota 55386, (US)
LEGAL REPRESENTATIVE:
Hughes, Andrea Michelle (75891), Frank B. Dehn & Co., European Patent Attorneys, 179 Queen Victoria Street, London EC4V 4EL, (GB)
PATENT (CC, No, Kind, Date): EP 972538 A2 000119 (Basic)
EP 972538 A3 001220
APPLICATION (CC, No, Date): EP 99111970 990625;
PRIORITY (CC, No, Date): US 114493 980713
DESIGNATED STATES: CH; DE; FR; LI; NL; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
INTERNATIONAL PATENT CLASS: A61N-001/36; A61N-001/05
ABSTRACT EP 972538 A2
A system for providing medical electrical stimulation to a portion of

the nervous system. The system includes a rigid hollow needle 105 having a lumen 104, a flexible lead body 102disposed within the lumen of the needle, the lead body having a insulated coiled proximal section and an electrode section 103, the proximal section comprising a conductor 115 which is coiled and insulated, the electrode section comprises a portion of the coiled conductor which is not insulated. In an alternative embodiment the electrode section features a crimp core 113 around which a distal end of the coiled conductor which is not insulated is crimped, the rigid hollow needle is metal but which is partially covered along its outer surface with an insulation. In still further embodiments the flexible lead body has a stylet lumen therein and the lead body also has a connector pin 101 for electrically connecting the electrical conductor to a pulse generator. Preferably this connector pin located on a proximal end of the lead body and having a diameter no greater than the inner diameter of the needle. **A method of providing temporary electrical stimulation to the sacral nerve is also disclosed.**

ABSTRACT WORD COUNT: 196
NOTE: Figure number on first page: 3
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	200003	501
SPEC A	(English)	200003	3329
Total word count - document A			3830
Total word count - document B			0
Total word count - documents A + B			3830

8/3,AB/2 (Item 2 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

00952354
Sacral medical electrical lead
Sakrale medizinische elektrische Zuleitung
Electrode medicale sacree
PATENT ASSIGNEE:
MEDTRONIC, INC., (209274), 7000 Central Avenue N.E., Minneapolis, Minnesota 55432, (US), (Applicant designated States: all)
INVENTOR:
Moumane, Farid, 1 Rue Aristide Briand, 59132 Trelon, (FR)
Robinet, Jean, 14 Rue Albert 1ER, 59186 Anor, (FR)
Deruyver, Benoit, 19 Rue Cambresienne, 59440 Avesnes-Sur-Helpe, (FR)
Mezera, Ronald Lee, 3017 Carlsbad Court, Burnsville, Minnesota 55337, (US)
LEGAL REPRESENTATIVE:
Hughes, Andrea Michelle (75891), Frank B. Dehn & Co., European Patent Attorneys, 179 Queen Victoria Street, London EC4V 4EL, (GB)
PATENT (CC, No, Kind, Date): EP 862925 A2 980909 (Basic)
EP 862925 A3 991201
APPLICATION (CC, No, Date): EP 98301389 980225;
PRIORITY (CC, No, Date): US 811054 970303
DESIGNATED STATES: CH; FR; GB; IT; LI; NL; SE
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
INTERNATIONAL PATENT CLASS: A61N-001/05
ABSTRACT EP 862925 A2

A sacral medical electrical lead 100 which may be implanted and reliably fixed for a temporary period of time within the sacrum in a minimally invasive manner. The lead features a lead body 102 having a

electrical conductor 119 positioned within an insulator sheath 120, a connector 101 for electrically coupling the electrical conductor to a pulse generator, an electrode 103 located on a distal end of the lead body, the electrode electrically coupled to the conductor, and an anchor 104 for anchoring the lead body to sacral tissue, the anchor integral with the insulator sheath. In the preferred embodiment the anchor comprises a notched section 110 in which the insulation of the lead body presents a macroscopically roughened surface which can thereby engage into the tissue without causing damage to the tissue.

ABSTRACT WORD COUNT: 134
NOTE: Figure number on first page: 3
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	9837	436
SPEC A	(English)	9837	2143
Total word count - document A			2579
Total word count - document B			0
Total word count - documents A + B			2579

8/3,AB/6 (Item 4 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
(c) 2002 WIPO/Univentio. All rts. reserv.
00562486
A METHOD TO CONTROL AN OVERACTIVE BLADDER
METHODE PERMETTANT DE REGULER L'HYPERACTIVITE DE LA VESSIE
Patent and Priority Information (Country, Number, Date):
Patent: WO 200025859 A1 20000511 (WO 0025859)
Application: WO 99DK589 19991029 (PCT/WO DK9900589)
Priority Application: DK 981396 19981030
Designated States: AE AL AM AT AT AU AZ BA BB BG BR BY CA CH CN CU CZ CZ DE DE DK DK EE EE ES FI FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SK SL TJ TM TR TT UA UG US UZ VN YU ZA ZW GH GM KE LS MW SD SL SZ TZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 3039
English Abstract
This application concerns a method to control an overactive bladder and to estimate bladder volume, comprising **an implanted sensor**, which **sensor comprises at least one nerve electrode to sense electrical signals, means for stimulation of nerves to inhibit detrusor contraction, an electronic unit to detect events from nerve signals and generate electrical pulses for stimulating nerves**. The object of the invention is treatment of involuntary loss of urine (incontinence) due to involuntary detrusor contractions (detrusor overactivity). Another object of the invention is estimation of bladder volume. This finds particular application in patients who use aids to empty their bladder e. g. intermittent catherisation or electrical stimulation.

8/3,AB/7 (Item 5 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT
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00556567
INCONTINENCE TREATMENT DEVICE
DISPOSITIF DE TRAITEMENT DE L'INCONTINENCE

Patent and Priority Information (Country, Number, Date):
Patent: WO 200019940 A1 20000413 (WO 0019940)
Application: WO 99IL529 19991005 (PCT/WO IL9900529)
Priority Application: US 98167244 19981006; IL 127481 19981209
Designated States: AE AL AM AT AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ CZ
DE DE DK DK DM EE EE ES FI FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG
KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE
SG SI SK SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW GH GM KE LS MW SD
SL SZ TZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB
GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 11546
English Abstract

A device (20) and method for treatment of urinary stress incontinence. At least one electrode (27) is implanted in a pelvic muscle of a patient. A control unit (22) receives signals indicative of abdominal stress in the patient and responsive thereto applies an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

8/3,AB/8 (Item 6 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00556566
CONTROL OF URGE INCONTINENCE
CONTROLE DE L'INCONTINENCE INSTANTE
Patent and Priority Information (Country, Number, Date):
Patent: WO 200019939 A1 20000413 (WO 0019939)
Application: WO 99IL528 19991005 (PCT/WO IL9900528)
Priority Application: US 98167244 19981006; IL 127481 19981209
Designated States: AE AL AM AT AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ CZ
DE DE DK DK DM EE EE ES FI FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG
KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE
SG SI SK SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW GH GM KE LS MW SD
SL SZ TZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB
GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 9906
English Abstract

A device (20) for treatment of a patient's urinary incontinence, including a sensor (44), which generates a signal responsive to a physiological characteristic indicative of a likelihood of incontinence. A control unit (22) receives the signal from the sensor. At least one electrode (29) is preferably implanted in the patient. The electrode is coupled to cause contraction of a pelvic muscle of the patient responsive to application of electrical energy to the electrode. Responsive to the signal, the control unit applies an electrical waveform to the electrode, so as to inhibit the incontinence.

8/3,AB/9 (Item 7 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00537947
IMPLANTABLE STIMULATOR SYSTEM AND METHOD FOR TREATMENT OF URINARY INCONTINENCE
SYSTEME DE STIMULATION IMPLANTABLE ET PROCEDE DE TRAITEMENT DE L'INCONTINENCE URINAIRE

Patent and Priority Information (Country, Number, Date):
Patent: WO 200001320 A2 20000113 (WO 0001320)
Application: WO 99US14775 19990629 (PCT/WO US9914775)
Priority Application: US 9891762 19980706
Designated States: AU CA JP US AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
Publication Language: English
Fulltext Word Count: 3105
English Abstract

A method and system for treatment of urinary incontinence includes the injection or laparoscopic implantation of one or more battery- or radiofrequency-powered microstimulators (10) beneath the skin of the perineum. The devices are programmed using radio-frequency control via an external controller (20, 30) that can be used by a physician to produce patterns of output stimulation pulses judged to be efficacious by appropriate clinical testing to diminish incontinence symptoms. The stimulation program is retained in the microstimulator device (10) or external controller (20) and is transmitted when commanded to start and stop by a signal from the patient or caregiver. The system and method reduce the incidence of unintentional episodes of bladder emptying by stimulating nerve pathways (8) that diminish involuntary bladder contractions, improve closure of the bladder outlet, and/or improve the long-term health of the urinary system by increasing bladder capacity and emptying. Further, the system and method allow a patient to be taught to receive one or more patterns of neural stimulation that can be prescribed by a physician and administered without continuous oversight by a clinical practitioner.

8/3,AB/11 (Item 9 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00447462
BATTERY-POWERED PATIENT IMPLANTABLE DEVICE
DISPOSITIF IMPLANTABLE SUR UN PATIENT ET FONCTIONNANT SUR BATTERIE
Patent and Priority Information (Country, Number, Date):
Patent: WO 9837926 A1 19980903
Application: WO 98US3687 19980225 (PCT/WO US9803687)
Priority Application: US 9739164 19970226
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GE GH GM GW HU ID IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW GH GM KE LS MW SD SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 9250
English Abstract

This invention is a device configured for implanting beneath a patient's skin for the purpose of tissue, e.g., nerves or muscle, stimulation, and/or parameter monitoring, and/or data communication. Devices in accordance with the invention are comprised of a sealed housing (110), typically having an axial dimension of less than 60 mm and a lateral dimension of less than 6 mm, containing a power source (104) for powering electronic circuitry within, including a controller (130), an address storage means (132), a data signal receiver, and an input/output transducer.

8/3,AB/12 (Item 10 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00378114

SYSTEM AND METHOD FOR CONDITIONING PELVIC MUSCULATURE USING AN IMPLANTED MICROSTIMULATOR

SYSTEME ET PROCEDE DE TRAITEMENT DE LA MUSCULATURE PELVIENNE AU MOYEN D'UN MICROSTIMULATEUR IMPLANTE

Patent Applicant/Assignee:
ADVANCED BIONICS CORPORATION,
RICHMOND Frances J R,
LOEB Gerald E,
Inventor(s):
RICHMOND Frances J R,
LOEB Gerald E,

Patent and Priority Information (Country, Number, Date):
Patent: WO 9718857 A1 19970529
Application: WO 96US18680 19961120 (PCT/WO US9618680)
Priority Application: US 957521 19951124
Designated States: AL AM AT AU AZ BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GE HU IL IS JP KE KG KP KR KZ LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK TJ TM TR TT UA UG US UZ VN KE LS MW SD SZ UG AM AZ BY KG KZ MD RU TJ TM AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 5111

English Abstract

A system and method for conditioning pelvic muscle tissue for the purpose of treating urinary incontinence uses one or more tiny implantable stimulators (20) - termed "microstimulators" - implanted in or near certain pelvic structures so as to contact target muscle tissue. The microstimulators (20) are small enough to allow their implantation using a hypodermic needle (104). Once implanted, the microstimulators (20) are controlled using a controller (105, 106) and an appropriate coupling coil (102) that couples modulated radio frequency (RF) power into the microstimulators. A fitting station (110) facilitates adjusting the stimulus pattern and amplitude to best meet the needs of a given patient. Once fitted, electrical stimulation is thus provided to the target tissue in accordance with a specified externally-controlled exercise or other regime.

File 155:MEDLINE(R) 1966-2002/JAN W2
File 144:Pascal 1973-2002/Dec W5
File 5:Biosis Previews(R) 1969-2001/Dec W5
File 6:NTIS 1964-2002/Jan W3
File 2:INSPEC 1969-2002/Jan W1
File 8:Ei Compendex(R) 1970-2002/Jan W1
File 99:Wilson Appl. Sci & Tech Abs 1983-2001/Nov
File 238:Abs. in New Tech & Eng. 1981-2001/Dec
File 65:Inside Conferences 1993-2002/Jan W1
File 77:Conference Papers Index 1973-2001/Nov
File 73:EMBASE 1974-2002/Dec W5
File 34:SciSearch(R) Cited Ref Sci 1990-2002/Jan W1
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
File 94:JICST-EPlus 1985-2002/Nov W4
File 35:Dissertation Abs Online 1861-2001/Dec
Set Items Description

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S1      105186   NEUROSTIMULAT??? OR NEURO()STIMULAT??? OR STIMULAT???(3N)N-
              ERVE? ?
S2     1352224   URIN?
S3      100592   FECAL?
S4      435244   SEXUAL
S5       16009   PELVIC()(PAIN OR FLOOR)
S6        9979   PAIN(3N)(PELVIS OR PELVIC)
S7        3870   S1 AND S2:S6
S8        2255   S1(S)S2:S6
S9      748762   IMPLANT?
S10        253   S8 AND S9
S11       1120   S1(3N)S9
S12         91   S10 AND S11
S13         33   RD (unique items)
S14          9   S13/2001
S15          7   S13/2000
S16         17   S13 NOT S14:S15
S17         17   Sort S16/ALL/PY,D

 17/7/1     (Item 1 from file: 144)
DIALOG(R)File 144:Pascal
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  14213084   PASCAL No.: 99-0413728
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Neuromodulation by implant for treating lower urinary tract symptoms and dysfunction

BEMELMANS B L H; MUNDY A R; CRAGGS M D
Department of Urology, University Hospital Nijmegen, Netherlands; Institute of Urology, University College London Medical School, London, United Kingdom

Journal: European urology, 1999, 36 (2) 81-91
ISSN: 0302-2838 CODEN: EUURAV Availability: INIST-16847; 354000085581740010
No. of Refs.: 51 ref.
Document Type: P (Serial) ; A (Analytic)
Country of Publication: Switzerland
Language: English

Objective: Patients with irritative micturition complaints, pelvic pain, involuntary urine loss or urinary retention are sometimes difficult to treat. The advent of direct sacral nerve stimulation offers a therapeutic alternative if conservative measures fail and surgery is considered. **This paper reviews therapeutic neuromodulation by implant for treating lower urinary tract symptoms and dysfunction.** Methods: The international literature is reviewed on topics such as the physiological basis of neuromodulation, techniques of acute testing and chronic implantation, and clinical results. Future developments and ways for possible improvement are discussed. Results: The mode of action of neuromodulation is probably through restoring the correct balance between excitatory and inhibitory impulses from and to the pelvic organs at a sacral and supra-sacral level. Depending on the predefined success criteria, average success rates of definitive implants vary from 50 to 70%. From the data it seems that patients with urge incontinence and urinary retention are the best candidates for neuromodulation. In the literature the lack of standardisation of selection criteria, stimulation parameters and definitions of success is striking. Conclusions: Neuromodulation by implant is a useful therapeutic alternative. It should at least be considered in patients with therapy-resistant urge incontinence and urinary retention before proceeding to surgery. Issues

such as underlying physiologgy, methodological standardisation, technical improvements, and patient selection must be addressed in future research.

17/7/2 (Item 2 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
10208329 99305273 PMID: 10378928
Battery-powered implantable nerve stimulator for chronic activation of two skeletal muscles using multichannel techniques.
Lanmuller H; Sauermann S; Unger E; Schnetz G; Mayr W; Bijak M; Rafolt D; Girsch W
Department of Biomedical Engineering and Physics, University of Vienna, Austria. H.LANMUELLER@BMTP.AKH-WIEN.AC.AT
Artificial organs (UNITED STATES) May 1999, 23 (5) p399-402, ISSN 0160-564X Journal Code: 8ZK
Languages: ENGLISH
Document type: Journal Article
Record type: Completed
Chronic activation of skeletal muscle is used clinically in representative numbers for diaphragm pacing to restore breathing and for dynamic graciloplasty to achieve fecal continence. **The 3 different stimulation techniques currently used for electrophrenic respiration (EPR) all apply high frequency powered implants. It was our goal to make these stimulation methods applicable for EPR by a battery-powered nerve stimulator that would maximize the patient's freedom of movement.** Additionally, the system should allow the implementation of multichannel techniques and alternating stimulation of 2 skeletal muscles as a further improvement in graciloplasty. Generally, the developed implantable nerve stimulator can be used for simultaneous and alternating activation of 2 skeletal muscles. Stimulation of the motor nerve is achieved by either single channel or multichannel methods. Carousel stimulation and sequential stimulation can be used for graciloplasty as well as for EPR. For EPR we calculated an operating time of the implant battery of 4.1 years based on the clinically used stimulation parameters with carousel stimulation. The multichannel pulse generator is hermetically sealed in a titanium case sized 65 x 17 mm (diameter x height) and weighs 88 g.
Record Date Created: 19990730

17/7/5 (Item 5 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
10069401 99130458 PMID: 9931666
Treatment of insufficiency of the anal sphincter by sacral spinal nerve stimulation with implantable neurostimulators]
Behandlung der Analsphinkterinsuffizienz durch sakrale Spinalnervenstimulation mit implantierten Neurostimulatoren.
Matzel KE; Stadelmaier U; Hohenfellner M; Hohenberger W
Chirurgische Klinik mit Poliklinik, Universitat Erlangen.
Langenbecks Archiv fur Chirurgie (GERMANY) 1998, 115 p494-7, ISSN 0942-2854 Journal Code: BAD
Languages: GERMAN
Document type: Journal Article
Record type: Completed
The feasibility of permanent electrostimulation of the sacral spinal nerves was studied in patients with fecal incontinence and no detectable morphological lesions and thus not amenable to conventional surgical management. Applying acute percutaneous stimulation with needle electrodes, the most relevant sacral spinal nerve for striated sphincter muscle function was identified (sacral

spinal nerve S3 or S4). The therapeutic potential of stimulation was tested by subchronic stimulation with temporary wire electrodes and, if effective, permanent electrodes were implanted in four patients. Long-term sacral spinal nerve stimulation persistently improved anal continence and increased the function of the striated muscular anal sphincter.
Record Date Created: 19990407

17/7/6. (Item 6 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
09860621 98339667 PMID: 9677013
Modern surgical treatment of anal incontinence.
Christiansen J
Department of Surgery, Herlev Hospital, University of Copenhagen, Denmark.
Annals of medicine (ENGLAND) Jun 1998, 30 (3) p273-7, ISSN 0785-3890 Journal Code: AMD
Languages: ENGLISH
Document type: Journal Article; Review; Review, Tutorial
Record type: Completed
New surgical treatment modalities have been developed for patients with anal incontinence resulting from extensive sphincter destruction and in whom standard sphincter repair has failed. **These new modalities include the transposition of striated skeletal muscles combined with implantation of neurostimulators, artificial sphincters based on the same principle as artificial urinary sphincters, and direct sacral nerve stimulation.** In a few reported series muscle transposition in combination with neurostimulation has given a satisfactory continence in 50-70% of the patients. The same is true for the smaller series published on artificial anal sphincters, whereas the results of sacral nerve stimulation have thus far been reported in only a few patients. The selection of patients and the performance of these procedures should be limited to few specialist centres. (30 Refs.)
Record Date Created: 19980925

17/7/7 (Item 7 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
09857590 98385510 PMID: 9720556
Bilateral chronic sacral neuromodulation for treatment of lower urinary tract dysfunction.
Hohenfellner M; Schultz-Lampel D; Dahms S; Matzel K; Thuroff JW
Department of Urology, University of Mainz, Germany.
Journal of urology (UNITED STATES) Sep 1998, 160 (3 Pt 1) p821-4, ISSN 0022-5347 Journal Code: KC7
Languages: ENGLISH
Document type: Journal Article
Record type: Completed
PURPOSE: Chronic sacral neuromodulation aims at functional restoration of selected forms of nonneurogenic and neurogenic bladder dysfunction. The original technique, as described by Tanagho and Schmidt, provides unilateral sacral nerve stimulation via an implanted stimulator powering an electrode inserted into a sacral foramen. Its drawback was that the implant failed unpredictably in some patients despite previous successful percutaneous test stimulation. Therefore, we modified the stimulation technique to improve the efficacy of chronic sacral neuromodulation. MATERIALS AND METHODS: Guarded bipolar electrodes powered by an implantable neurostimulator were attached bilaterally directly to the S3 nerves through a sacral laminectomy in 9 women and 2 men (mean age 43.4 years). Of the patients 5 had urinary incontinence due to detrusor hyperactivity and 6 had urinary retention from detrusor hypocontractility. Mean followup with

repeated urodynamics was 13 months (range 9 to 28). RESULTS: Four significant complications were encountered in 4 patients. In 10 patients the urological sequelae of the neurological disorder were alleviated significantly (50% or more), including 5 who experienced complete relief of symptoms. CONCLUSIONS: **The efficacy of chronic sacral neuromodulation can be improved by bilateral attachment of electrodes directly to the sacral nerves.**
Record Date Created: 19980924

17/7/11 (Item 11 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
08800557 96068470 PMID: 7587546
Permanent electrostimulation of sacral spinal nerves with an implantable neurostimulator in treatment of fecal incontinence]
Permanente Elektrostimulation der sacralen Spinalnerven mit einem implantierbaren Neurostimulator zur Behandlung von Stuhlinkontinenz.
Matzel KE; Stadelmaier U; Hohenfellner M; Gall FP
Chirurgische Klinik mit Poliklinik, Universitat Erlangen-Nurnberg.
Der Chirurg; Zeitschrift fur alle Gebiete der operativen Medizen (GERMANY) Aug 1995, 66 (8) p813-7, ISSN 0009-4722 Journal Code: D5U
Languages: GERMAN
Document type: Journal Article
Record type: Completed
Functional deficits of the striated muscular anal sphincter frequently result in faecal incontinence. The therapeutic options for patients without a defined muscular defect are limited. Our patient without defined lesion, but with a clinically relevant reduction of the voluntary force of the anal sphincter resulting in daily loss of stool, underwent an electrostimulation procedure of the sacral spinal nerves. **The procedure was divided in three steps: acute percutaneous testing, temporary percutaneous nerve evaluation and permanent electrostimulation phase with an implantable neurostimulation device.** In all three phases electrostimulation of the third sacral spinal nerve resulted in a positive clinical effect and an increase of the anal canal closure pressure. By application of permanent electrostimulation of the third sacral spinal nerve the patient became completely continent.
Record Date Created: 19951201

17/7/13 (Item 13 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)

07889608 BIOSIS NO.: 000092138898
CONSTIPATION ASSOCIATED WITH CHRONIC SPINAL CORD INJURY THE EFFECT OF PELVIC PARASYMPATHETIC STIMULATION BY THE BRINDLEY STIMULATOR
AUTHOR: BINNIE N R; SMITH A N; CREASEY G H; EDMOND P
AUTHOR ADDRESS: UNIV. DEP. SURGERY, WESTERN GEN. HOSP., EDINBURGH, UK.
JOURNAL: PARAPLEGIA 29 (7). 1991. 463-469. 1991
FULL JOURNAL NAME: Paraplegia
CODEN: PRPLB
RECORD TYPE: Abstract
LANGUAGE: ENGLISH
ABSTRACT: Ten subjects with severe constipation due to complete spinal cord injury (SCI) had prolonged oro-anal transit time ($p < 0.01$), diminished faecal water content ($p < 0.05$) and a reduced frequency of defaecation ($p < 0.01$) compared to 10 non-SCI subjects. **Paraplegic with an implanted Brindley S234 anterior sacral nerve root stimulator** had a significant increase in frequency of defaecation ($p < 0.01$), compared to the SCI group while the faecal water content was less although not significantly

so. The Brindley stimulator group also showed a more rapid colonic transit than the SCI group but this did not reach statistical significance. SCI is associated with constipation which therefore appears to be favourably influenced by the Brindley S234 anterior nerve root stimulator. The effects produced are compatible with stimulation of left colonic motility, which facilitates the emptying of the distal colon, but also sugest that part of the response restricts transit in some areas of the colon or rectum. Since the motility changes induced by the Brindley stimulator do not affect the right colon a relatively greater residence time of the faecal bolus in this part of the large bowel would enhance water absorption.

17/7/14 (Item 14 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
05237321 88236866 PMID: 3259746
An implantable radio-controlled sacral nerve root stimulator for control of urination]
Implanterbar , radiostyret sakralrodstimulator til kontrolleret vandladning.
Nordling J; Hald T; Kristensen JK; Schmidt K; Gjerris F
Ugeskrift for laeger (DENMARK) Apr 18 1988, 150 (16) p978-80, ISSN 0041-5782 Journal Code: WM8
Languages: DANISH
Document type: Journal Article
Record type: Completed
Record Date Created: 19880624

17/7/15 (Item 15 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)

03365141 BIOSIS NO.: 000022008237
PERMANENT PER CUTANEOUS DEVICES
AUTHOR: VON RECUM A F; PARK J B
AUTHOR ADDRESS: INQ.: WILLIAM C. HALL, SOUTHWEST RES. INST., SAN ANTONIO, TEXAS.
JOURNAL: CRIT REV BIOENG 5 (1). 1981. 37-77. 1981
FULL JOURNAL NAME: Critical Reviews in Bioengineering
CODEN: CRBEA
DOCUMENT TYPE: Review
RECORD TYPE: Citation
LANGUAGE: ENGLISH

17/7/16 (Item 16 from file: 73)
DIALOG(R)File 73:EMBASE

01671742 EMBASE No: 1980103056
Surgical therapy of chronic pain
Long D.M.
Dept. Neurosurg., Johns Hopkins Med. Inst., Baltimore, Md. United States
Neurosurgery (NEUROSURGERY) (United States) 1980, 6/3 (317-328)
CODEN: NRSRD
DOCUMENT TYPE: Journal
LANGUAGE: ENGLISH
Surgical therapy for chronic pain remains an important part of the management of the patient incapacitated by a wide variety of painful states. The surgical treatments can generally be grouped into those aimed

at the peripheral nerve, the sympathetic nervous system, the spinal cord, and a variety of structures within the brain. Direct peripheral nerve surgery is valuable in a limited number of patients, with success rates of about 40%. **Implanted peripheral nerve stimulators are highly effective**, but are useful only in a small group of patients who respond to percutaneous nerve stimulation . Sympathectomy is curative in causalgia and has been reported to be effective for pain of biliary, pancreatic, and renal origin. It is not useful in the poorly defined reflex sympathetic dystrophy syndromes. Cordotomy remains the most important pain-relieving procedure, but is useful only in the treatment of pain of malignant disease. Late failure and the development of dysesthesias make it of little value in the management of chronic pain of a benign origin. Spinal cord stimulation has been used in a limited group of patients, and success rates of 50 to 70% have been achieved. Technical problems with the electronic devices limit the usefulness of the technique significantly. Midline myelotomy is a valuable procedure for pelvic pain . Destructive operations in the brain stem, thalamus, and cerebrum are of no value in the management of chronic pain. Stimulation in the upper brain stem and thalamus has been used in a small number of patients; success rates as high as 60 to 80% have been reported. The rationale of the technique is still not understood and it is used only by a few surgeons with a major dedication to the therapy of pain. **Radiofrequency techniques have added a new dimension to pain therapy; trigeminal neuralgia is now effectively treated by radiofrequency neurotomy. Surgical procedures remain an effective part of pain therapy**. They are most useful for specific problems, such as trigeminal neuralgia or causalgia, and for the pain of malignant disease. No good surgical therapies for pain of a benign origin that can be applied ubiquitously are available. The majority of surgical procedures for pain provide relief to a small percentage of the patients so treated and should be utilized only with careful patient selection. This patient selection should include a complete psychological characterization of the patient.

17/7/17 (Item 17 from file: 2)
DIALOG(R)File 2:INSPEC

00682647 INSPEC Abstract Number: B74035292
Title: Nerve stimulation by implanted microwave diode
Author(s): Johnson, C.C.; Lords, J.L.; Coombs, M.A.
Author Affiliation: Univ. Utah, Salt Lake City, UT, USA
Conference Title: Microwave Symposium. Digest of Technical Papers p. 30-1
Publisher: IEEE, New York, NY, USA
Publication Date: 1974 Country of Publication: USA x+381 pp.
Conference Sponsor: IEEE
Conference Date: 12-14 June 1974 Conference Location: Atlanta, GA, USA
Language: English Document Type: Conference Paper (PA)
Treatment: Applications (A); Experimental (X)
Abstract: Damage to nerves in the body can cause loss of voluntary muscle function, such as the arms and legs, and loss of involuntary muscle function such as heart contraction, control of urination, etc. In many cases, if appropriate nerves could be stimulated by external means, these functions could be restored. **This paper describes experimental work to develop an extremely small implanted device which, when located close to a viable impaired nerve, can restore its function**. The device is activated by RF electromagnetic waves passing through the skin which do not damage the intervening tissue. (4 Refs)
Subfile: A B

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File  98:General Sci Abs/Full-Text 1984-2001/Nov
File   9:Business & Industry(R) Jul/1994-2002/Jan 03
File  16:Gale Group PROMT(R) 1990-2002/Jan 07
File 160:Gale Group PROMT(R) 1972-1989
File 148:Gale Group Trade & Industry DB 1976-2002/Jan 04
File 621:Gale Group New Prod.Annou.(R) 1985-2002/Jan 07
File 636:Gale Group Newsletter DB(TM) 1987-2002/Jan 07
File 441:ESPICOM Pharm&Med DEVICE NEWS 2002/Dec W3
File  20:Dialog Global Reporter 1997-2002/Jan 08
File 813:PR Newswire 1987-1999/Apr 30
File  15:ABI/Inform(R) 1971-2002/Jan 05
File  88:Gale Group Business A.R.T.S. 1976-2002/Jan 04
Set     Items   Description
S1       5736   NEUROSTIMULAT??? OR NEURO()STIMULAT??? OR STIMULAT???(3N)N-
            ERVE? ?
S2      91556   URIN?
S3       9958   FECAL?
S4     247411   SEXUAL
S5       2258   PELVIC()(PAIN OR FLOOR)
S6     118450   IMPLANT?
S7       1431   PAIN(3N)(PELVIC OR PELVIS)
S8         19   S1(3N)S6(S)(S2:S5 OR S7)
S9         14   RD (unique items)
S10         2   S9/2001
S11    970627   PD=20001115:20001231
S12        12   S9 NOT S10:S11
S13        12   Sort S12/ALL/PD,D

 13/8/12      (Item 12 from file: 160)
DIALOG(R)File 160:(c) 1999 The Gale Group. All rts. reserv.
01789537
Cordis' Secor patient-controlled implantable drug delivery device
October 12, 1987
COMPANY: *Cordis DUNS: 00-412-1059 TICKER: CORD (NYSE) CUSIP: 218525
PRODUCT: *Implanted Drug Infusion Systems (3841557)
EVENT:   *Product Design & Development (33)
COUNTRY: *United States (1USA)

 13/7/1      (Item 1 from file: 636)
DIALOG(R)File 636:Gale Group Newsletter DB(TM)
(c) 2002 The Gale Group. All rts. reserv.
04770525    Supplier Number: 65016538  (THIS IS THE FULLTEXT)
UROLOGY: Sacral Nerve Treatment Safe.
Medical Materials Update, v7, n7, pNA
August, 2000
TEXT:
Sacral nerve stimulation from an implant is a safe and effective for
people who suffer from urinary urgency-frequency and who have not
responded favorably to more traditional treatment options, such as pelvic
muscle exercises, biofeedback, medications, and surgeries, reports a study
reported in the Journal of Urology.
     The article reported results from a 12-center multinational study
assessing the efficacy of Medtronic's (7000 Central Ave. NE, Minneapolis,
MN 55432; Tel: 763/574-4000, Fax: 763/574-4879) InterStim sacral nerve
```

stimulation therapy in treating patients with urgency-frequency. Almost all candidates had previously undergone medical treatment that had failed to alleviate their symptoms.

The InterStim device uses neurostimulation to send mild electrical pulses to the sacral nerves in the lower back. A neurostimulator, about the size of a stopwatch, is surgically placed under the skin of the abdomen and generates pulses carried by a thin implanted lead, or wire, to the sacral nerves, which control bladder function. Physicians can non-invasively adjust the strength of stimulation to a level that helps each patient the most.

An estimated 17 million American men and women suffer from the urinary control problems of urge incontinence and urgency- frequency. The approximately 9 million Americans with urgency- frequency feel an uncontrollable urge to empty their bladder--some more than 40 times a day.

Although a variety of treatments--drugs, biofeedback, and surgeries--are available, many people with urgency-frequency and other urinary control problems do not respond well to them. Medtronic estimates that tens of thousands of patients in the group could benefit from the InterStim device.

The 51 patients selected had shown a satisfactory response to a test stimulation before the study began. They were then divided into a control group (26 people) who received standard medical treatment and a stimulation group (25 people) that received sacral nerve stimulation using InterStim.

After six months of treatment, the stimulation group experienced significant improvement in three key areas: number of voids daily, volume of urine per void, and degree of urgency before void. (The term void refers to the natural, physiological process of emptying the bladder.)

Other points:

Compared with those patients who did not receive InterStim therapy, the stimulation group, on average, reported fewer limitations in physical activities, less pain, and less difficulty with work or other daily activities due to health.

Patients in the study who had received InterStim therapy continued to have significantly improved efficiency in bladder storage and emptying and reduced pelvic/bladder discomfort at 12 months, compared to baseline. Long-term results demonstrated sustained clinical benefit in the 21 patients who were followed through 2 years after implant of the device.

About one-third of the patients who received the InterStim device underwent subsequent surgery to reposition or replace elements of their systems. The adjustments were intended to resolve device or therapy-related adverse side effects. The most commonly reported adverse events included pain at the neurostimulator site (15.3%), pain (9.0%), and lead migration(8.4%).

13/7/2 (Item 2 from file: 88)
DIALOG(R)File 88:Gale Group Business A.R.T.S.

05333908 SUPPLIER NUMBER: 59579589
Sacral Nerve Stimulation Tames Urge Incontinence.
LINDSAY, HEATHER
OB GYN News, 35, 1, 11
Jan 1, 2000
TEXT:

Sacral nerve stimulation using a surgically implanted device can

significantly curb urinary urge incontinence in patients refractory to standard medical therapy.

At a 6-month follow-up, 47% of 34 patients who used the device were completely dry, and another 28% had at least a 50% reduction in incontinence episodes, reported Dr. Richard A. Schmidt of the University of Colorado Health Science Center in Denver and his associates.

Before the study began, 125 women and 30 men who had frequent, severe urge incontinence refractory to medical therapy underwent a 3-to 7-day test period of sacral nerve stimulation to quantify the effects of trial stimulation on dysfunctional voiding behavior.

Of these patients, 98 had a greater than 50% improvement in baseline voiding (J. Urol. 162(2):352-57, 1999).

These 98 patients were randomized to undergo either standard medical therapy or surgical implantation of the device, which sends mild electrical pulses to the sacral nerves in the lower back that influence bladder function. The device may be turned on or off after implantation, the investigators said.

Of 76 patients who were evaluable after 6 months of therapy, the 34 patients in the device group had fewer and less severe daily incontinence episodes than the 42 controls.

Of the treated patients, 16 were completely dry, 10 had at least a 50% reduction in incontinence episodes, 5 had a slight reduction, 2 had an increase in episode frequency, and 1 required device explantation due to pain.

However, when stimulation was discontinued for several days at the 6-month point, patients quickly returned to baseline levels of incontinence.

The controls showed no change in their condition.

Of 21 patients who used the device and were followed for up to a total of 18 months, 76% had at least a 50% reduction in leakage episodes. Nearly a third of the original 155 patients had complications requiring surgical intervention to adjust the device, most often pain at the neurostimulator site or implant site.

There were no reports of permanent nerve damage.

The study was funded by Medtronic Inc., maker of the implanted device, which is marketed as InterStim therapy for urinary control.

13/7/3 (Item 3 from file: 98)
DIALOG(R)File 98:General Sci Abs/Full-Text

03757142 H.W. WILSON RECORD NUMBER: BGSI98007142 (THIS IS THE FULLTEXT)
Incontinence implant approved.
FDA Consumer v. 32 (Jan./Feb. 1998) p. 6
LANGUAGE: English
COUNTRY OF PUBLICATION: United States
WORD COUNT: 266
ABSTRACT: **On September 29, 1997, the FDA approved the Sacral Nerve Stimulation System, an implantable nerve stimulator to treat urge incontinence.** This sudden, uncontrollable loss of urine is caused by involuntary bladder wall contractions. **The battery-operated implant, which is made by Medtronic Inc. of Spring Lake Park, Minnesota, consists of a pacemaker-size generator for implanting in the abdominal wall and a wire lead for connecting to the nerves near the sacrum, the large bone at the bottom of the spine.** Of the 5 million adults who suffer from urge incontinence, 20 percent may benefit from the new treatment.

TEXT:

Adults who suffer a serious type of urinary incontinence have a new treatment option: an implantable nerve stimulator .

FDA approved the Sacral Nerve Stimulation System last Sept. 29 to treat urge incontinence. This sudden, uncontrollable loss of urine is due to involuntary bladder wall contractions, which may result from such nerve conditions as spinal cord injury, stroke, and multiple sclerosis, or from other bladder problems. The device requires major surgery and is for use only when less invasive treatments, such as drugs and diet changes, fail. Of the 5 million adults, mainly women, who experience urge incontinence, 20 percent may benefit from the new treatment.

The battery-operated device consists of a pacemaker-size generator for implanting in the abdominal wall and a wire lead for attaching to the nerves near the sacrum, the large bone at the bottom of the spine. The generator sends electric impulses along the lead to the sacral nerves to help control bladder contractions.

After six months into clinical studies of 86 implanted patients, 47 percent of patients were dry, and an additional 28 percent had 50 percent fewer leakage episodes. Results were similar after 12 months and 18 months. In safety studies of 157 implanted patients, about a third had problems requiring at least a second surgery. Doctors could usually resolve the most common problem, pain, by repositioning the device.

The manufacturer, Medtronic Inc., of Spring Lake Park, Minn., must do a five-year study of the device to determine long-term effects.

13/7/6 (Item 6 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

05171558 Supplier Number: 47892692 (THIS IS THE FULLTEXT)
NEW MEDTRONIC THERAPY FOR URINARY INCONTINENCE RECOMMENDED BY FDA ADVISORY COMMITTEE: Approximately 5 million incontinent Americans could benefit from new therapy
News Release, pN/A
August 6, 1997
TEXT:
MINNEAPOLIS, MN, August 6, 1997 -- **Medtronic, Inc. (NYSE: MDT), announced that a new treatment using electrical stimulation to manage urge incontinence was recommended unanimously for marketing clearance today by the Gastroenterology - Urology Devices Advisory Panel to the U.S. Food and Drug Administration (FDA)**. in the United States, it is estimated by the Agency for Health Care Policy and Research that 13 million adults suffer from incontinence, at an estimated cost to the health care system of $11.2 billion annually. Approximately 40 percent of the total incontinent patient population, five million people, experience urge incontinence. Urge incontinence is a sudden loss of urine associated with an abrupt urge to void that cannot be inhibited. Of the various types of incontinence, urge incontinence is particularly troublesome because of the unpredictability of leaking episodes. Patients live in constant fear that they will suffer public humiliation, or not have access to a toilet or a change of pad/clothing. "Incontinence is a tragic embarrassment to millions in our society and there is tremendous demand for effective treatments to improve the physical and emotional health of these patients," said Rob ten Hoedt, business director of Medtronic Interstim. "Medtronic is hopeful that the FDA will act on the panel's recommendation and make Sacral Nerve Stimulation therapy available to millions of incontinent patients as quickly as possible." **Sacral Nerve Stimulation (SNS) therapy is a**

revolutionary approach to the treatment of urge incontinence, offering a reversible and non-destructive treatment. It is the only treatment designed to address the problem of urge incontinence internally at the origin of the sacral nerve reflexes that control the behavior of the bladder, sphincter, and pelvic floor . The therapy works by applying electrical stimulation to the sacral nerves via a totally implantable system, including a lead and an implantable pulse generator. SNS therapy is designed to offer patients a new treatment option that can be tailored on a case- by-case basis by physicians to optimize results for each patient. Potential adverse effects of the therapy can include the risk of the surgical procedure and infection associated with any surgical procedure. Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, specializing in implantable and interventional therapies. The Medtronic Internet address is www.medtronic.com. >EN

13/7/10 (Item 10 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

05566747 SUPPLIER NUMBER: 11702386 (THIS IS THE FULL TEXT)
Practical Urology in Spinal Cord Injury. (book reviews)
Milroy, Euan
Lancet, v338, n8776, p1192(1)
Nov 9, 1991
TEXT:

There is little doubt that spinal-cord injuries are best treated in specialist units, but acutely injured patients are likely to need emergency treatment outside such centres, and transfer to a spinal injury unit may not always be possible. This short and highly readable book, the latest in the Clinical Practice in Urology series, gives much useful advice to clinicians who are faced with unfamiliar problems in the management of spinal cord injury.

Parsons and Fitzpatrick have brought together an experienced international group of authors and have successfully persuaded them to keep contributions short and practical. Each chapter has a comprehensive list of references for further reading, and the absence of extensive theoretical detail can easily be remedied by reference to one of several large textbooks of clinical neurourology that have recently been published. There are very good chapters on the immediate management of spinally injured patients and on the associated urological problems. Detailed consideration is given to urinary tract dilatation, stones, and infection, with an excellent chapter on the psychological and practical considerations of sexual function and fertility. The section on the urodynamic evaluation of these patients is helpful and avoids unnecessary mathematics or theoretical physics. **Recent innovations and future possibilities, including various implantable nerve stimulators, are covered in the final chapter; the Brindley stimulator, the most widely used device to achieve efficient bladder emptying and continence in these patients, is discussed at length.**

Practical Urology in Spinal Cord Injury is indeed a fair description of this book. It should be read by urologists in training and by any other clinicians who look after people with spinal injuries, and could probably be read with interest and benefit by many of these unfortunate patients themselves.

EUAN MILROY
Department of Urology, Middlesex Hospital, London W1N 8AA, UK

13/3,AB,K/5 (Item 5 from file: 636)
DIALOG(R)File 636:Gale Group Newsletter DB(TM)

03712352 Supplier Number: 48020354
U.S. HHS: FDA approves implanted device to control incontinence
M2 Presswire, pN/A
Oct 1, 1997
Language: English Record Type: Fulltext
Document Type: Newswire; Trade
Word Count: 640
RDATE:300997

The Food and Drug Administration today approved an implanted nerve stimulator to treat a serious type of urinary incontinence in adults.
The device is intended for women and men who have urge incontinence...

13/3,AB/7 (Item 7 from file: 148)
DIALOG(R)File 148:Gale Group Trade & Industry DB

08333303 SUPPLIER NUMBER: 17609454 (USE FORMAT 7 OR 9 FOR FULL TEXT)
Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence
Matzel, Klaus E.; Stadelmaier, U.; Hohenfellner, M.; Gall, F.P.
Lancet, v346, n8983, p1124(4)
Oct 28, 1995
ISSN: 0099-5355 LANGUAGE: English RECORD TYPE: Fulltext; Abstract
WORD COUNT: 2402 LINE COUNT: 00204
ABSTRACT: **Electrically stimulating the sacral spinal nerves may improve fecal incontinence in patients with dysfunctional anal muscles.** Fecal incontinence happens when stool passes involuntarily, often due to a decrease in anal and rectal muscle control. Researchers electrically stimulated the spinal nerves at the lower end of the spine in three patients with fecal incontinence. Examination indicated no particular physical defect in the rectum. **Electrode stimulation was temporary at first and later permanently installed via an implant.** After six months, two patients had achieved full continence and the third person experienced only slight soiling. Average squeezing pressures of the anal canal increased in all three patients. Although patients reported slight twitching sensations in the pelvic and anal areas initially, electrical stimulation was well tolerated.
AUTHOR ABSTRACT: Functional deficits of the striated anal sphincteric muscles without any apparent gross defect often result in a lack of ability to postpone defaecation by intention or in faecal incontinence in response to increased intra-abdominal or intra-rectal pressure. We applied electrostimulation to the sacral spinal nerves to increase function of the striated muscles of the anal sphincter. Of three patients followed for 6 months, two gained full continence and one improved from gross incontinence to minor soiling. Closure pressure of the anal canal increased in all. Preliminary data indicate that anal closure pressure increases with the duration of stimulation. Continuous stimulation of sacral spinal nerves can help some patients with faecal incontinence. It may be possible to promote continence with intermittent stimulation.

13/3,AB,K/11 (Item 11 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

01554985 Supplier Number: 41902346

Neuroprosthetics Recommended For Relieving Chronic Pelvic Pain
Urology Times, p21
March, 1991
Language: English Record Type: Fulltext
Document Type: Magazine/Journal; Trade
Word Count: 578 (USE FORMAT 7 FOR FULLTEXT)
TEXT:
SAN FRANCISCO - Permanent implantation of neurostimulators in the lower urinary tract can provide "dramatic" relief from chronic pain in many patients who fail to respond...

File 350:Derwent WPIX 1963-2001/UD,UM &UP=200201
File 344:CHINESE PATENTS ABS APR 1985-2001/Oct
File 347:JAPIO OCT 1976-2001/Aug(UPDATED 011203)
File 371:French Patents 1961-2001/BOPI 200151
Set Items Description
S1 6 AU="SPINELLI M" [not relevant]

File 348:EUROPEAN PATENTS 1978-2001/DEC W02
File 349:PCT FULLTEXT 1983-2002/UB=20020103,UT=20011227
>>>No sets currently exist
[The inventors were not in any of the foreign patent databases searched.]

File 5:Biosis Previews(R) 1969-2001/Dec W5
File 9:Business & Industry(R) Jul/1994-2002/Jan 02
File 15:ABI/Inform(R) 1971-2002/Jan 05
File 16:Gale Group PROMT(R) 1990-2002/Jan 04
File 18:Gale Group F&S Index(R) 1988-2002/Jan 03
File 20:Dialog Global Reporter 1997-2002/Jan 07
File 34:SciSearch(R) Cited Ref Sci 1990-2002/Jan W1
File 42:Pharmaceuticl News Idx 1974-2001/Dec W3
File 43:Health News Daily 1990-2002/Jan 04
File 47:Gale Group Magazine DB(TM) 1959-2002/Jan 03
File 71:ELSEVIER BIOBASE 1994-2002/Jan W1
File 73:EMBASE 1974-2002/Dec W5
File 88:Gale Group Business A.R.T.S. 1976-2002/Jan 04
Set Items Description
S1 115 MEDTRONIC AND INTERSTIM
S2 87 RD (unique items)
S3 0 S2/2001 AND S2/2000
S4 57 S1/TI,DE
S5 42 S2 AND S4
S6 31 S1/2001
S7 19 S2/2000
S8 22 S2/2001
S9 46 S2 NOT S7:S8
S10 26 S4 AND S9

10/6/1 (Item 1 from file: 16)
07615634 Supplier Number: 62280018 (USE FORMAT 7 FOR FULLTEXT)
Study cites effects of **InterStim** on urge.(urinary incontinence research)(Brief Article)
Sept, 1999
Word Count: 324

10/6/2 (Item 2 from file: 16)
07615408 Supplier Number: 62279732 (USE FORMAT 7 FOR FULLTEXT)
Expanded indications okayed for **InterStim** .(Brief Article)
May, 1999
Word Count: 483

10/6/3 (Item 3 from file: 16)
06309145 Supplier Number: 54528217 (USE FORMAT 7 FOR FULLTEXT)
Life's Better Now, Say Most Patients Whose **InterStim** Devices Treat Serious Bladder Control Problems.
May 3, 1999
Word Count: 458

10/6/5 (Item 5 from file: 16)
06000512 Supplier Number: 53384062 (USE FORMAT 7 FOR FULLTEXT)
Medtronic Applauds AUA for Incontinence Awareness Program; Its **InterStim Continence Control Therapy is New Option in Treatment Continuum.**
Dec 10, 1998
Word Count: 210

10/6/6 (Item 6 from file: 16)
05260122 Supplier Number: 48015486
It's another thumbs up by FDA at Medtronic .
Sept 30, 1997

10/6/8 (Item 8 from file: 16)
05190824 Supplier Number: 47921089 (USE FORMAT 7 FOR FULLTEXT)
Medtronic Reports Earnings Per Share Up 18.9 Pct. as Implantable Defibrillators, Neuro Devices Spur Results
August 19, 1997
Word Count: 782

10/6/9 (Item 9 from file: 16)
05172453 Supplier Number: 47893898
New Medtronic Therapy for Urinary Incontinence Recommended by FDA Advisory Committee
August 6, 1997
Word Count: 435

10/6/10 (Item 1 from file: 42)
00676377 49778897
Least burdensome draft guidance would unduly increase RCTs -- Medtronic
December 20, 1999

10/6/11 (Item 2 from file: 42)
00674201 48028444
HCFA winnows panel agenda to pelvic floor stimulation, biofeedback
November 8, 1999

10/6/12 (Item 3 from file: 42)
00669569 0669569
Trial backs incontinence device
August 16, 1999

10/6/13 (Item 4 from file: 42)
00659809 0659809

FDA April 1999 report of medical device approvals: 27;Premarket approval supplements
May 24, 1999

10/6/14 (Item 5 from file: 42)
00656991 0656991
Medtronic Interstim labeling expansion addresses 3 mil. added patients
April 26, 1999

10/6/15 (Item 6 from file: 42)
00644213 0644213
FDA November 1998 report of medical device approvals: 16;Premarket approval supplements
December 21, 1998

10/6/16 (Item 7 from file: 42)
00632593 0632593
FDA July 1998 report of medical device approvals: 36;Premarket approval supplements
August 31, 1998

10/6/18 (Item 9 from file: 42)
00604412 0604412
FDA's October 1997 report of medical device approvals: 13;Premarket approval supplements
December 1, 1997

10/6/21 (Item 12 from file: 42)
00602413 0602413
Medtronic Insterstim urge incontinence device as 12-rep dedicated U.S. sales force
November 10, 1997

10/6/22 (Item 13 from file: 42)
00601347 0601347
FDA's September 1997 report of medical device approvals: 4;Premarket approvals
October 27, 1997

10/6/23 (Item 14 from file: 42)
00599648 0599648
Medtronic 's continence control device gets go-ahead in US
October 6, 1997

10/6/24 (Item 15 from file: 42)
00599477 0599477
Medtronic Interstim urge incontinence treatment expected to be in 100 U.S. centers by April 1998; Shipments commence Nov. 1 after Sept. 29 PMA approval
October 6, 1997

10/6/25 (Item 1 from file: 43)
00031836 F-D-C Accession Number 03101310000 -- July 9, 1998
Medicare Commission members to visit Medtronic , United Healthcare, dual-eligible seniors clinic during Minneapolis field hearing July 13.

10/7/4 (Item 4 from file: 16)

DIALOG(R)File 16:Gale Group PROMT(R)

06276386 Supplier Number: 54404162 (THIS IS THE FULLTEXT)
Medtronic Announces FDA Approval of InterStim (R) Therapy for Urinary Control.
PR Newswire, p2782
April 19, 1999
TEXT:

FDA Approval of Indications Offers Revolutionary New Treatment for Retention, New Hope for Patients Suffering From Severe Bladder Control Problems

MINNEAPOLIS, April 19 /PRNewswire/ -- Medtronic , Inc. (NYSE: MDT), **today announced approval by the U.S. Food and Drug Administration (FDA) of InterStim (R) Therapy for Urinary Control for the treatment of urinary retention (without mechanical obstruction), as well as for significant symptoms of urgency-frequency.** The approval of this therapy also heralds the introduction of a new treatment alternative for patients with retention, whose previous treatment options were limited to a lifetime of self-catheterization.

(Photo: http://www.newscom.com/cgi-bin/prnh/19990419/MNM004 http://www.newscom.com/cgi-bin/prnh/19990419/MNM004-b)

An estimated 13 million American men and women suffer from urinary control problems. Approximately 85 percent of those who suffer are women between the ages of 30 and 59 -- women who are in the most active, productive years of their lives. For these women, the effects of incontinence are especially debilitating.

InterStim Therapy is indicated for those who suffer from symptoms of urinary urge incontinence, urinary retention or significant symptoms of urgency-frequency. Those with urinary urge incontinence or significant symptoms of urgency-frequency may feel a strong urge to urinate as many as 40 times a day and often are embarrassed by wetting episodes. Although a variety of drug therapies are available to them, many people do not respond well to medication and are often resigned to managing their condition with absorbent diapers or pads. People with urinary retention have difficulty emptying their bladder completely. They have few therapy options and manage their condition by self-catheterization.

InterStim Therapy uses neurostimulation to send mild electrical pulses to the sacral nerves in the lower back that control bladder function. A stopwatch-sized neurostimulator, placed under the skin of the abdomen, generates mild pulses that are carried via a thin implanted lead, or wire, to the sacral nerves.

Based upon the electrical stimulation technology pioneered by Medtronic for pacemakers and adapted to address neurological conditions such as tremor, InterStim Therapy represents a new category of bladder control treatment, one that many physicians and patients may choose before resorting to bladder augmentation, bladder removal or other irreversible surgical options. A simple diagnostic trial or test stimulation initiated in a physician's office can help assess whether InterStim Therapy will prove effective.

" InterStim Therapy offers new hope to people suffering the debilitating physical and psychological effects of severe types of bladder control problems," said Dr. Richard Schmidt, of the University of Colorado Health Center's Division of Urology and the lead investigator of the FDA clinical study. "In addition to causing embarrassment, bladder control problems can impair the ability of its sufferers to care for family, hold a job or enjoy activities that many of us take for granted."

"In clinical trials, InterStim Therapy proved highly effective in alleviating the symptoms of urinary urge incontinence, urgency-frequency

and urinary retention," said Schmidt. In the trials:

-- After 12 months of InterStim Therapy, 82 percent of urgency-frequency patients experienced increased volumes of urine voided with the same or a reduced degree of urgency, meaning they felt urgency only when their bladders needed to emptied, rather than continually.

-- After six months, 47 percent of patients with urinary urge incontinence were completely dry, and 77 percent reported that they no longer experienced unexpected, heavy wetting episodes;

-- After six months of the therapy, 53 percent of patients with urinary retention no longer needed a catheter.

"Before receiving InterStim Therapy, these patients were so severely debilitated that they were unable to leave home, work, exercise or participate in routine activities," said Schmidt. "With InterStim Therapy, patients experienced fewer physical limitations and less difficulty with work or other daily activities. They reported a significant improvement in quality of life."

Dr. Lindsey A. Kerr, a Vermont urologist who is the spokesperson for the National Association for Continence, an organization committed to improving the quality of life of people with incontinence, said, "It is estimated that there are more than 13 million incontinent people in the United States. Many of them are untreated, living in shame and fear. We are pleased any time a new product comes on the market to provide us with another option in the treatment of urinary incontinence. InterStim Therapy is not meant as a first- line device, but is an excellent fit for those with severe incontinence that don't respond well to drugs or other therapies."

In addition to allowing patients to test its potential effectiveness before surgical placement of the neurostimulator, InterStim Therapy offers other key benefits. Physicians can non-invasively adjust the strength of stimulation to maximize its benefit for each patient. If InterStim Therapy fails to provide satisfaction, it can be turned off or removed.

Risks associated with InterStim Therapy include, but are not limited to, the risk of the surgical procedure and infection associated with it. Possible side effects associated with the therapy, including pain, infection and lead migration, are typically resolvable.

"For 50 years, Medtronic has pioneered the use of electrical stimulation in the treatment of cardiac arrhythmias," said John Meslow, president of Medtronic 's neurological division. "Over the past two decades, we have successfully developed neurostimulation to address other health needs, including the treatment of chronic pain and the control of tremor. We are delighted today to introduce the benefits of neurostimulation to people who suffer from severe forms of incontinence. InterStim Therapy can help many of them regain their ability to function and live full lives."

More information on InterStim Therapy can be requested by calling toll free to 800-664-5111, extension 3000, or by visiting the InterStim Web site at http://www. interstim .com

Medtronic , Inc., headquartered in Minneapolis, is the world's leading medical technology company specializing in implantable and interventional therapies. Its Internet address is http://www. medtronic.com

A video news release featuring InterStim will be available via satellite feed at the following times and coordinates on Monday, April 19, 1999:

10-10:30 a.m., EST - C-Band, Telstar4/Transponder 20
1-1:30 p.m., EST - C-Band, Galaxy 6/Transponder 9
4-4:15 p.m., EST - C-Band, Galaxy 6/Transponder 9

10/7/7 (Item 7 from file: 16)
DIALOG(R)File 16:Gale Group PROMT(R)

05259385 Supplier Number: 48014263 (THIS IS THE FULLTEXT)
FDA Gives Medtronic Clearance to Market Revolutionary Treatment for Incontinence
PR Newswire, p0929MNM026
Sept 29, 1997
TEXT:
MINNEAPOLIS, Sept. 29 /PRNewswire/ -- Medtronic , Inc. (NYSE: MDT) today announced **clearance by the U.S. Food and Drug Administration to market Interstim (R) Continence Control Therapy, the first implantable treatment ever to use electrical stimulation of the sacral nerves to manage urinary urge incontinence.**

It is estimated by the Agency for Health Care Policy and Research that approximately 13 million Americans suffer from urinary incontinence, costing the nation's health care system an estimated $11.2 billion annually. Of incontinence sufferers, approximately five million people suffer from urge incontinence -- strong, sudden urges to urinate followed by the involuntary losses of urine. This form of incontinence is particularly distressing for people because of the unpredictability of the frequency and severity of these leaking episodes. While it affects both men and women, more than 85 percent of sufferers in this country are women between the ages of 30 and 59.

"Urinary incontinenceis a serious medical condition that can be emotionally crushing and prevent people from performing basic daily activities, including work and sleep," said Steven Siegel, MD, of Metropolitan Urologic Specialists in Minneapolis, Minn. "With Medtronic 's Interstim Continence Control Therapy, these individuals could see some real improvement in their quality of life, regaining control not only of their bodily functions but also regaining self-esteem and confidence."

" Interstim Continence Control Therapy is another example of Medtronic 's commitment to utilizing our electrical stimulation technology to meet the unmet medical needs of patients worldwide," said William George, chief executive officer of Medtronic , Inc. "We applaud the FDA for this expedited review process which ensures that life-enhancing products and therapies are available to patients as soon as possible. Interstim Continence Control Therapy offers incontinence sufferers improved quality of life through continence control."

With the FDA approval to market the procedure, Medtronic is launching an extensive physician training and education program that will make the therapy more widely available to U.S. incontinence sufferers over the next several months.

Similar to the way a pacemaker delivers electrical stimulation to the heart, the Interstim Continence Control Therapy uses electrical pulses to help control bladder function -- avoiding or at least reducing accidental urination or leakage. It currently is being used by physicians and their patients in Europe, Canada, Australia, Africa and the Middle East.

"The therapy is proven to be highly effective with nearly half of the patients in the clinical trial reporting total dryness after receiving Interstim Continence Control Therapy," said Dr. Siegel. "Further, three out of four trial participants experienced at least a 50 percent reduction in leakage episodes and severity of leaks."

The therapy, a minimally invasive procedure, works by applying electrical stimulation to the sacral nerves (located at the base of the

spine) via a totally implantable system, including a lead and pulse generator, or pacemaker-like device. Interstim Continence Control Therapy is designed to offer patients a new treatment that can be tailored on a case-by-case basis by physicians, such as adjusting stimulation frequency and strengths, to maximize therapy benefits. It is a completely reversible treatment and does not preclude other medical interventions.

Depending on the patient, Interstim Continence Control Therapy can be used instead of, or in conjunction with, more conservative therapies, such as physical therapy, drug therapy and biofeedback.

Potential adverse effects of the therapy can include the risk of the surgical procedure and infection associated with any surgical procedure.

Patients interested in the Interstim Continence Control Therapy should consult their physician or a urologist to discuss risks and benefits and to assess whether this therapy is appropriate for them. For more information, patients and physicians can call 800-664-5111, extension 3000.

Medtronic , Inc., headquartered in Minneapolis, is the world's leading medical technology company specializing in implantable and interventional therapies. Interstim Continence Control Therapy is offered by the Medtronic Neurological Business. The Medtronic Internet address is .www. medtronic .com

SOURCE Medtronic , Inc.

-0- 9/29/97

/CONTACT: Ursula Guise or Dare Hurley both of Ketchum Public Relations, 415-984-6336 or 6261, for Medtronic ; Christopher O'Connell, Investor Relations, 612-514-4971 or Jessica Stoltenberg, Corporate Communications, Medtronic , Inc., 612-514-3333, both of Medtronic /

/Company News On-Call: http://www.prnewswire.com or fax, 800-758-5804, ext. 551393/

/Web site: http://www. medtronic .com/

(MDT)

CO: Medtronic , Inc.; Food and Drug Administration

ST: Minnesota

IN: MTC HEA

SU: PDT

ES-KG

-- MNM026 --

7874 09/29/97 16:56 EDT http://www.prnewswire.com

10/7/26 (Item 2 from file: 43)
DIALOG(R)File 43:Health News Daily

00029220 F-D-C Accession Number 03091900003
Health News Daily -- October 1, 1997
Volume 9, Issue 190

Medtronic's Interstim implanted pulse generator for urge incontinence approved eight months after PMA submission.

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File 350:Derwent WPIX 1963-2001/UD,UM &UP=200201
File 344:CHINESE PATENTS ABS APR 1985-2001/Oct
File 347:JAPIO OCT 1976-2001/Aug(UPDATED 011203)
File 371:French Patents 1961-2001/BOPI 200151
Set     Items   Description
S1       1133   NEUROSTIMULAT??? OR NEURO()STIMULAT??? OR STIMULAT???(3N)N-
            ERVE? ?
S2      23888   URIN?
S3        761   FECAL?
S4       3157   SEXUAL
S5         91   PELVIC()(PAIN OR FLOOR)
S6         36   PAIN(3N)(PELVIS OR PELVIC)
S7         13   S6 NOT  S5
S8          0   S1 AND S7


File 348:EUROPEAN PATENTS 1978-2001/DEC W02
File 349:PCT FULLTEXT 1983-2002/UB=20020103,UT=20011227
Set     Items   Description
S1       1989   NEUROSTIMULAT??? OR NEURO()STIMULAT??? OR STIMULAT???(3N)N-
            ERVE? ?
S2      29012   URIN?
S3       3256   FECAL?
S4       4917   SEXUAL
S5        357   PELVIC()(PAIN OR FLOOR)
S6        169   PAIN(3N)(PELVIC OR PELVIS)
S7         29   S6 NOT S5
S8          1   S1(S)S7 [not relevant]
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S10/4, 7, 26

w3.medtronic.com/neuro/interstim/fr_phys.html

× model 3080 & 3886 Leads manual

① insert needle - posterior of sacrum
② guide needle ⓐ into foramen
③ dilate insertion path
④ remove needle
⑤ insert stimulatem lead
⑥ remove dilator

to anchor stimulatem lead

⑦ incision from epidermis to a fascia layer
⑧ anchor s.l. to f.l. w/ suture anchor

Directions for Use

Resterilization

The lead and accessories of the Model 3886 or Model 3080 Lead Kit were sterilized with ethylene oxide before shipment. Inspect the sterile package for seal integrity and damage to the package before opening and using the contents. If you are unsure of the components' sterility for any reason, they can be resterilized at the hospital site.

> **Note:** If contamination is suspected because of a defective sterile package seal, leads and accessories can be returned to Medtronic for replacement or they can be resterilized at the hospital. Replacements are otherwise subject to the terms of the Medtronic Limited Warranty (U.S. Customers). Medtronic does not accept returned leads or accessories for resterilization and return them to customers.

Due to variations in hospital sterilizers, precise instructions for sterilization or aeration cannot be given here. If further information is necessary regarding the procedures to be used, contact the manufacturer of the sterilizer unit. Use biological indicators or other acceptable methods to assist in validating the effectiveness of the hospital's sterilizer unit.

Medtronic cannot accept the responsibility for the resterilization of any components. If, however, the decision is made to resterilize, usual and customary sterilization methods should be used.

⚠ Cautions

- Do not resterilize and use the leads or the accessories after exposure to body tissues or fluids.
- Do not use radiation to resterilize any component.
- Do not autoclave the lead or stylet.

Subject to the foregoing, the following may be considered:

Table 4 summarizes the resterilization options and restrictions. The paragraphs following the table provide additional information.

Table 4. Resterilization Options and Restrictions.

Component	Sterilization Methods[1]		
	Ethylene Oxide 130° F (55° C) Maximum	Autoclave 250° F (121° C) 15 psi 30 minutes	"Flash" Autoclave 270° F (132° C) 27 psi 5 minutes
Lead	YES	NO	NO
Stylets	YES	NO	NO
Connector Boot	YES	NO	NO
Other Accessories	YES	YES	YES

1 Medtronic cannot accept responsibility for the resterilization of any components at the hospital.

Ethylene oxide is an acceptable method for resterilization when the leads and accessories are repackaged in an ethylene oxide-permeable package. The temperature during the process should not exceed 130° F (55° C). The maximum possible aeration must be allowed before implanting the lead and using the accessories.

Steam autoclaving may also be used as a sterilization method for components marked YES for autoclave or "flash" autoclave in Table 4. For autoclave, a standard cycle of 30 minutes at 250° F (121° C) and 15 psi is recommended. For "flash" autoclave, a standard cycle of 5 minutes at 270° F (132° C) and 27 psi is recommended. Do not sterilize a component using any method that is marked NO for that component.

Suggested Implant Procedures

The Model 3886 and Model 3080 Leads are designed to be implanted adjacent to the sacral nerves. Intraoperative test stimulation is used to properly locate the target nerve with electrical stimulation.

Operating Room Supplies

In addition to standard surgical instruments and supplies selected by the physician, Medtronic recommends that the following supplies and instruments be on hand:

- Medtronic Model 3625 Test Stimulator, Medtronic Model 041827 Test Stimulation Cables, Medtronic Model 041831 Patient Cable, and Medtronic Model 041826 Ground Pads
- Medtronic Model 041828 or Model 041829 Foramen Needles
- 3-0 silk suture material (for securing lead anchor and lead)
- French Eye or Murphy needle (or equivalent size needle)
- Rubber-tipped forceps

Have the x-ray from the test stimulation available as a reference for positioning the lead.

For information on test stimulation, refer to the technical manual packaged with the test stimulation lead kit or test stimulation components.

Test Stimulator

Note: The test stimulator is not sterile and should be operated outside the sterile field.

1. Check that the test stimulator output (amplitude) is OFF (refer to the operator manual package with the test stimulator).

⚠ Warning

To help prevent possible uncomfortable patient stimulation, always turn the test stimulator amplitude OFF before connecting or disconnecting cables.

2. Remove the long test stimulation cable from the Medtronic Test Stimulation Cables and the patient cable from the Test Stimulation Lead Kit.

   Note: Two non-sterile cables are enclosed in the Medtronic Test Stimulation Cables; the long cable is used for intraoperative test stimulation.

3. Connect the long test stimulation cable and the patient cable as shown in Figure 4.
   a. Place the ground pad on the patient's skin and insert the pin end (red plug) of the long test stimulation cable into the ground pad.
   b. Insert the test stimulation cable into the test stimulator.
   c. Insert the patient cable into the black plug of the long test stimulation cable.

   Note: Ensure all cable connections are secure.

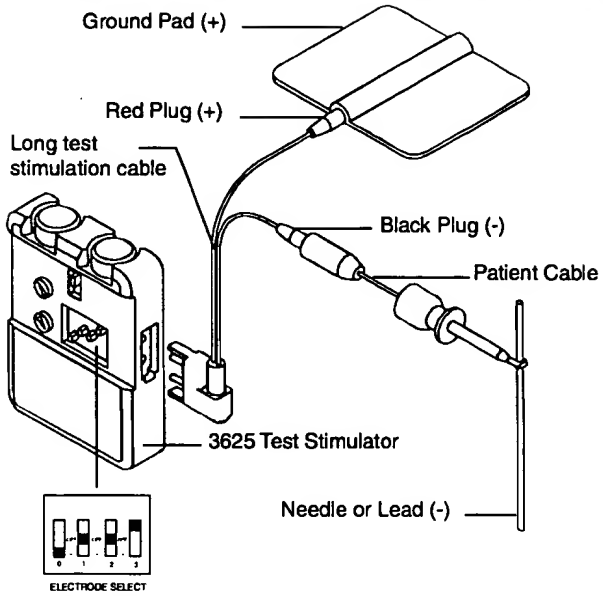

Figure 4. Test stimulator cable connections.

Preparation

1. Administer anesthesia to the patient.

   Note: Anesthesia and muscle relaxants can affect muscle responses.

2. Place the patient in a prone position allowing for a 30 degree flexion at the hip and knees.
3. Prepare the sacrum and perineum for sterile surgery.
4. Drape to allow observation of the pelvic floor for muscle response to test stimulation.
5. Provide visual access to soles of the feet to confirm muscle responses to stimulation.

Directions for Use

Acute Stimulation and Dissection

1. Confirm the desired foramen level that produced the best response during test stimulation.
   a. Using bony topography or fluoroscopy as a guide, insert the insulated foramen needle into the selected foramen.

⚠ Caution

Limit the depth and number of needle insertions into the foramen. Cease insertion at the point where the desired response is obtained. The insertion depth is usually 1.0 to 1.5 inches (2.5 to 4.0 cm).

   b. Connect the mini-hook from the patient cable to the non-insulated section of the foramen needle (black band below hub). Refer to Figure 4.
   c. Turn the test stimulator output (amplitude) ON.
   d. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the technical manual packaged with the test stimulation lead kit.
   e. Turn the test stimulator output (amplitude) OFF when finished with test stimulation.
2. Make a midline incision, appropriate to the size of the patient, with two-thirds of the incision above and one-third below the selected foramen.
3. Using appropriate surgical technique, dissect to expose the sacral foramen. Split and retract the spinal and paraspinal muscles; preserve the periosteum while separating the muscles.

Lead Preparation

1. If using the Model 3886 Lead, secure a lead anchor with nonabsorbable suture approximately 6 to 10 mm proximal to electrode 3 (Figure 5).

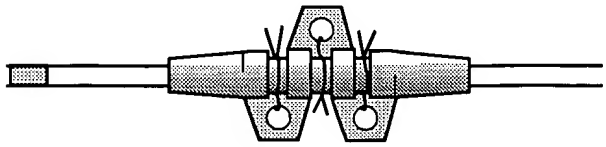

Figure 5. Secure anchor on Model 3886 Lead.

Note: Suturing too tightly will cut the lead anchor. Suturing too loosely will not adequately fixate the lead over time.

Lead Implantation

1. Test stimulate for proper responses using an insulated foramen needle.
   a. Connect the mini-hook from the patient cable to the non-insulated section of the foramen needle (black band below hub). Refer to Figure 4.
   b. Turn the test stimulator output (amplitude) ON.
   c. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the technical manual packaged with the test stimulation lead kit.
   d. Turn the test stimulator output (amplitude) OFF when finished with test stimulation.

Directions for Use

2. Remove the needle and immediately replace it with the lead.
   a. Insert the lead into the foramen at the site where the needle was removed. If necessary, puncture the fascia with rubber-tipped forceps.
   b. Aim the lead so that the tip (electrode 0) will follow the course of the nerve through the foramen.

⚠ Caution

Lateral lead placement may increase the risk of nerve injury or undesirable bowel effects, and should be avoided.

   c. Continue inserting the lead until the lead anchor contacts the periosteum. The insertion depth is usually 1.0 to 1.5 inches.

Note: The lead should maneuver easily. Upon release of the rubber-tipped forceps, the lead should stay in place and not spring back.

3. Carefully remove the long stylet from the lead (Figure 6).

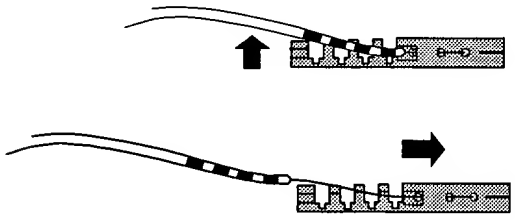

Figure 6. Disconnect and remove stylet handle and long stylet.

4. Test stimulate the various electrodes (0, 1, 2, 3) and observe responses. If necessary, reposition the lead.
   a. Connect the patient cable mini-hook to the lead contact.
   b. Turn the test stimulation output (amplitude) ON.
   c. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the technical manual packaged with the test stimulation lead kit.
   d. Turn the test stimulator output (amplitude) OFF when finished with test stimulation.

⚠ Caution

Optimal motor responses should be observed intraoperatively at 1 to 2 volts amplitude during test stimulation of the lead. If strong motor responses are obtained at amplitude levels measured at less than 1 volt intraoperatively, the lead may be placed too close to the intended sacral nerve, and should be repositioned farther away.

5. Use an appropriately sized needle and nonabsorbable suture material (or equivalent needle and suture combination) to fix the lead anchor to the periosteum (Figure 7). Appropriate needles include Murphy or French Eye needles.

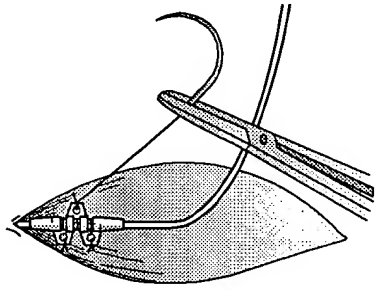

Figure 7. Anchor lead.

6. Test stimulate the various electrodes (0, 1, 2, 3) to confirm response previously observed.
7. If desired, determine the optimal placement for a second anchor and attach.
   a. Use nonabsorbable suture to attach the anchor to the lead.

   Note: Suturing too tightly will cut the lead anchor. Suturing too loosely will not adequately fixate the lead over time.

   b. Attach the lead anchor to the fascia using nonabsorbable suture.

   Note: Apply separate ties to fix the anchor to the lead and to fix the anchor to the fascia.

8. Suture the fascia to close the sacral incision.
9. Test stimulate the various electrodes (0, 1, 2, 3) to identify and record the electrode giving the best response (Figure 8).
   a. Connect the patient cable mini-hook to the lead contact.
   b. Turn the test stimulation output (amplitude) ON.
   c. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the technical manual packaged with the test stimulation lead kit.
   d. Turn the test stimulator output (amplitude) OFF when finished with test stimulation.

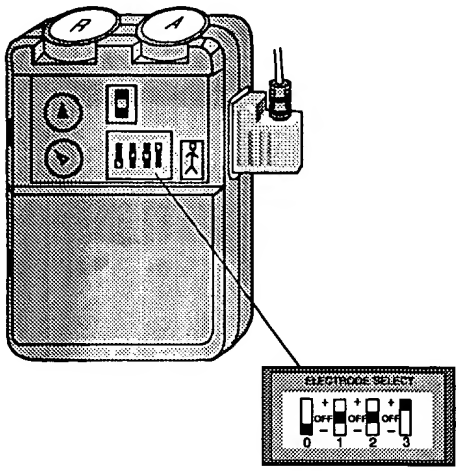

Figure 8. Model 3625 Test Stimulator.

Lead Tunneling

1. Hold the lead over the patient's skin to simulate its subcutaneous path to the extension-lead connection site. Mark the location of the connection site on the patient's skin.

   Note: Routing the lead to follow the pelvic girdle, below the iliac crest, may help to minimize torsional forces on the lead postoperatively.

2. Check that the tube is on the shaft of the tunneling tool.
3. Attach the metal tunneling tip (Figure 9).

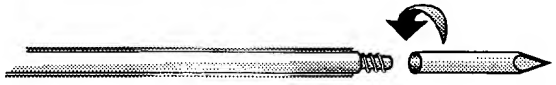

Figure 9. Attach metal tunneling tip.

4. Bend the tunneling tool as necessary to conform to the patient's contour.
5. Make a small stab wound at the extension-lead connection site.
6. Tunnel at the subcutaneous level from the sacral foramen to the connection site.

Note: Deep tunneling is not desirable.

7. Remove the tunneling tip and tunneling tool, leaving the tube in place in the tunnel.
8. Attach the enclosed short stylet to the proximal end of the lead. The short stylet is attached the same way as the long stylet (Figure 10).
   a. Insert the short stylet completely into the lead.
   b. Secure the lead in the stylet handle.

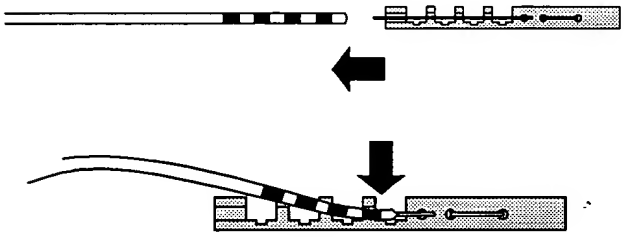

Figure 10. Attach short stylet to lead.

9. Attach a suitably stiff suture to the short stylet and pass it through the hole provided, leaving a long enough tail to pass through the tube (Figure 11).

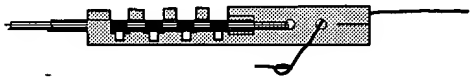

Figure 11. Attach suture to short stylet.

Note: To help pass the suture through the tube, apply suction at the tube exit or use the tunneling tool and tie the suture to its threaded tip.

10. Pull on the suture to draw the lead through the tube.
11. Test stimulate the various electrodes (0, 1, 2, 3) to confirm response previously observed.

12. Carefully disconnect and remove the short stylet from the lead.
13. Pull the tube out to remove it from the tunnel, leaving the lead in position.
14. Attach the silk tie with 5-cm tags to the end of the lead to identify its location after patient rotation.
15. Irrigate and close both incisions, the final closure of the sacral incision and the temporary closure of the lead-extension connection site, to accommodate patient rotation.

Tunneling to the Implant Site

1. Reposition the patient to the lateral decubitus position.
2. Prepare the patient's lower quadrant, flank, and connection site.
3. Drape to allow access to the lead connection site and the neurostimulator implant site.
4. Reopen the lead connection site and expose the proximal end of the lead. Test stimulate to confirm proper response.
   a. Connect the patient cable mini-hook to the lead contact.
   b. Turn the test stimulation output (amplitude) ON.
   c. Gradually increase the intensity of stimulation to obtain appropriate paresthesia or muscle response as outlined in the "Acute Stimulation" section of the technical manual packaged with the test stimulation lead kit.

⚠ Caution

Optimal motor responses should be observed intraoperatively at 1 to 2 volts amplitude during test stimulation of the lead. If strong motor responses are obtained at amplitude levels measured at less than 1 volt intraoperatively, the lead may be placed too close to the intended sacral nerve, and should be repositioned farther away.

d. Turn the test stimulator output (amplitude) OFF when the patient's response has been confirmed.
e. Disconnect the patient cable from the lead.
f. Disconnect the test stimulation cable from the ground pad and then the test stimulator.

5. Carefully remove the silk tags from the proximal end of the lead.
6. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is typically placed in the lower right or left quadrant.

Note: The neurostimulator should be located no more than 1.5 inches (3.8 cm) beneath the surface of the skin to ensure proper programming. The device must be placed parallel to the skin surface. The etched identification side of the neurostimulator must face away from muscle. If more than one IPG is used, they must be separated by a minimum of 8 inches (20 cm).

⚠ Caution

Place the neurostimulator away from bony structures and with the etched identification side facing away from muscle tissue to minimize pain at the neurostimulator site, and to minimize possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

7. Place the neurostimulator in the pocket to assure a proper fit and then remove it.

8. Provide a tunnel for the extension.
   a. Attach the wedge tip to the tunneling tool (Figure 12).

Figure 12. Attach wedge tip.

Note: A tunneling tool extender is provided in the extension kit for situations where the tunneling tool is not long enough. Remove the wedge tip and attach the extender using the extender wrench (Figure 13). Then attach the wedge tip.

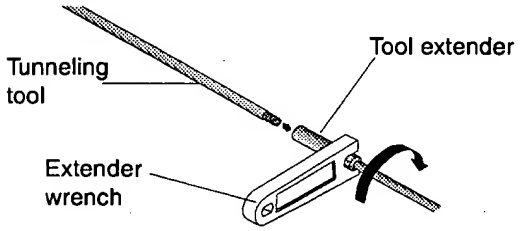

Figure 13. Attach tunneling tool extender.

   b. Bend the tunneling tool as necessary to conform to the patient's body contour.
   c. Tunnel from the lead-extension connection site to the neurostimulator pocket. Use caution when approaching the neurostimulator pocket to avoid additional trauma to the patient as resistance to tunneling suddenly ceases.

Note: An intermediate incision may be necessary if the tunneling tool does not extend the entire distance.

Making the Lead-Extension Connection

1. With the tunneling tool in place, remove the wedge tip and attach the carrier tip.
2. Insert the extension setscrew connector into the groove in the carrier tip (Figure 14). Carefully draw the assembly through the tunnel to where the lead lies exposed.

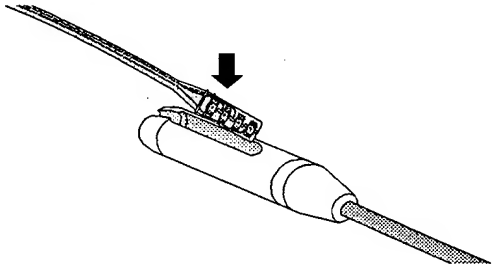

Figure 14. Insert extension setscrew connector into carrier tip.

3. Remove the extension setscrew connector from the carrier tip.

   Note: To aid in removing the connector, push the connector forward in the groove, then lift the connector to remove.

4. Push the protective boot over the proximal end of the lead (Figure 15) while stabilizing the lead body.

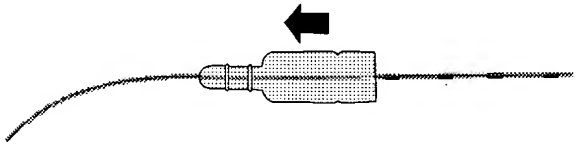

Figure 15. Push protective boot over lead.

5. Wipe off any remaining body fluids from the surface of the lead contacts and the extension setscrew connector.

Directions for Use

6. Insert the lead fully into the extension setscrew connector. The four metal bands on the lead should be aligned under the four setscrews (Figure 16).

   Note: Sterile water may be used as a lubricant to facilitate the insertion of the lead. This may also help to see the lead more clearly through the extension setscrew connector.

Figure 16. Insert lead into extension setscrew connector.

7. Tighten each of the four setscrews by turning them clockwise with the hex wrench provided (Figure 17). Tighten the setscrews only until they touch the contacts. Continue tightening to a maximum of 1/4 turn.

⚠ Cautions

- Do not overtighten the setscrews. Excessive torque on the setscrews may damage the lead contacts.
- Do not pull the lead body taut when implanted. The extension is available in different lengths. Select an extension length that allows connection without tension.

Note: The setscrews must engage the contacts before stimulation can be attempted.

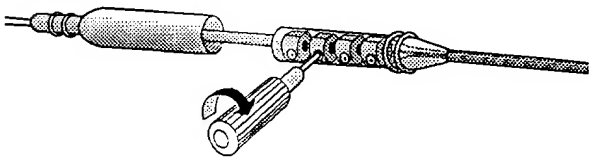

Figure 17. Tighten setscrews.

8. Push the protective boot completely over the lead-extension connection.

   Note: Sterile water may be used as a lubricant for ease of placing the boot.

9. Secure the connection with nonabsorbable sutures around the grooved ends of the connection (Figure 18).

⚠ Caution

Do not tie a suture directly to the extension or the lead body. If the suture is tied too tightly over other areas of the lead or extension bodies, the suture could cut through the insulation and cause a short.

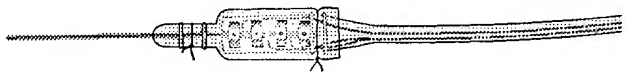

Figure 18. Suture both ends of connection.

10. Gently push the connected lead and extension into the incision.

    Note: Pull any excess extension length toward the neurostimulator pocket. The connection should lie straight in the subcutaneous plane with the lead and extension curving gently away.

11. Close and dress the wound.

Making the Extension-Neurostimulator Connection

1. Check the neurostimulator connector block and determine if any setscrews obstruct the socket. If necessary, partially back out the setscrews.
   a. To back out a setscrew, insert the hex wrench through the pre-pierced hole in the rubber grommet and turn the setscrew counterclockwise only until the socket is unobstructed (Figure 19).

⚠ Caution

Limit counterclockwise rotations of the setscrew. Rotate enough to provide an unobstructed pathway for extension connector pins. Too many rotations may disengage the setscrew from the neurostimulator connector block.

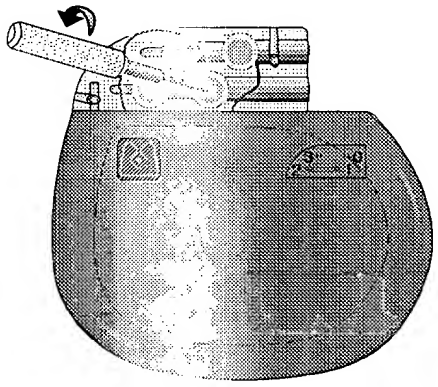

Figure 19. Turn setscrew counterclockwise to back out.

b. Wipe off any body fluids from the extension connector pins and connector block.
c. Check that the encapsulated diagram on the extension matches the diagram on the neurostimulator.
d. Insert the extension connector pins into the neurostimulator sockets and verify that the pins do not encounter any resistance (Figure 20).

Note: If inserting the extension pins is still difficult, use sterile water as a lubricant.

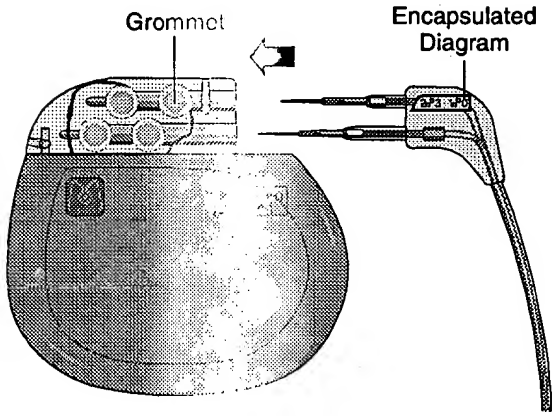

Figure 20. Insert extension connector pins.

2. After verifying that no setscrews obstruct the sockets, wipe off any body fluids from the extension connector pins or neurostimulator connector block.
3. Insert the extension connector pins into the neurostimulator sockets until the molded rubber contacts the neurostimulator connector block (Figure 20).

4. Once the extension connector pins are fully inserted in the neurostimulator sockets, do the following for each setscrew:
   a. Insert the hex wrench through the rubber grommet to engage the setscrew.
   b. Tighten the setscrew by turning clockwise with the hex wrench (Figure 21). Tighten the setscrews only until they touch the contacts.
   c. Continue tightening **for a maximum of 1/4 turn.**

⚠ Caution

- **Do not overtighten the setscrews. Excessive torque on the setscrews may damage the neurostimulator sockets. Verify that the sealing rubber grommet has closed.**
- **Discard the hex wrench after making all of the connections. The hex wrench is a single-use-only item. Its operation cannot be assured if it is used for multiple surgeries.**

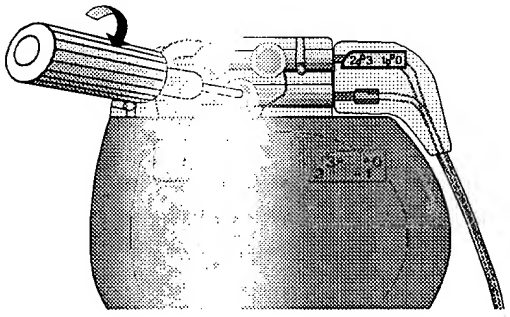

Figure 21. Tighten setscrews with hex wrench.

Note: The sealing rubber within the neurostimulator connector block assembly is designed to form a seal with the extension connector pins. No sealant or sutures are required.

5. Place the neurostimulator into the subcutaneous pocket on the anterior surface of the muscle. The etched identification side must face away from the muscle layer of the body (Figure 22). Position the neurostimulator so that no sharp bends occur along the extension lead (Figure 23).

⚠ Caution

Place the neurostimulator away from bony structures and with the etched identification side facing away from muscle tissue to minimize pain at the neurostimulator site, and to minimize possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

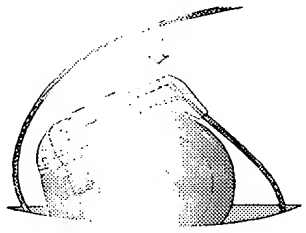

Figure 22. Place neurostimulator into subcutaneous pocket.

⚠ Caution

Do not loop or coil extension on top of the neurostimulator etched identification side. Wrap any excess length around perimeter of the neurostimulator (Figure 23). This avoids any increase in subcutaneous pocket depth, minimizes potential damage during replacement surgery, and minimizes potential kinking of extension.

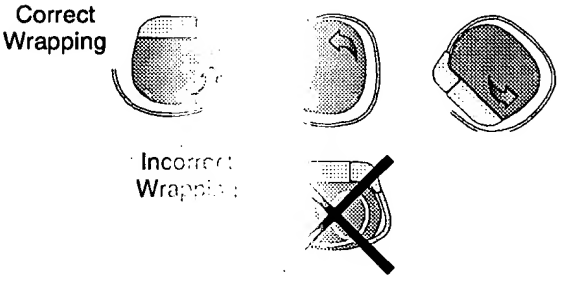

Figure 23. Excess length around perimeter of neurostimulator.